Daniel J. Kaiser, Esq.
William H. Kaiser, Esq.
KAISER SAURBORN & MAIR, P.C.
30 Broad Street, 37th Floor
New York, New York 10004
Telephone: (212) 338-9100
Facsimile: (212) 338-9088
Email: kaiser@ksmlaw.com
kaiserw@ksmlaw.com

Geoffrey R. Kaiser, Esq.
KAISER LAW FIRM, PLLC
926 RXR Plaza
Uniondale, New York 11556-0926
Telephone. (516) 570-3071
Facsimile: (516) 570-3071
Email: gkaiser@kaiserfirm.com

Attorneys for Plaintiff-Relator Mary Bixler Wood

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON AND THE DISTRICT OF COLUMBIA EX REL. MARY BIXLER WOOD,

Plaintiffs,

V.

SIEMENS MEDICAL SOLUTIONS USA, INC., SIEMENS HEALTHCARE DIAGNOSTICS, INC., AND SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH,

Defendants.

COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*] AND STATE FALSE CLAIM ACTS

JURY TRIAL DEMANDED

TABLE OF CONTENTS

Page

I. NATURE OF THE ACTION 4

II. PARTIES 8

III. JURISDICTION AND VENUE 9

IV. APPLICABLE LAW 10

A. The False Claims Acts 10

B. Regulatory Background Related to Medical Devices 13

a. FDA Approval and Clearance of Medical Devices Under the FDCA 14

b. FDA Quality System Regulations Ensure Compliance with Current Good Manufacturing Practices 17

c. Medical Device Labeling 19

C. Government Payments for IVDs 20

a. Federal Health Care Programs 20

i. Medicare 21

ii. Medicaid 22

iii. TRICARE (formerly CHAMPUS) 24

iv. CHAMPVA 25

b. Federal and State Purchasers of IVDs 26

c. Federal and State Agencies Pay Claims for Siemens IVDs Through Insurance Reimbursement and Direct Contract Payments 29

V. FACTS UNDERLYING SIEMENS ' DANGEROUS AND FRUADULENT MISCONDUCT 32

A. Siemens' own Stress Testing and Risk Assessments Revealed the Dangers of Exposing IVDs to Temperature Conditions Outside Their FDA-Approved Parameters 32

a. Stress Testing 32

b. Risk Assessments 33

B. Siemens' Knowingly Sipped Adulterated and Misbranded IVDs Outside FDA-Mandated Temperature Ranges in Order to Save Distribution Costs Despite Evidence That Doing So Would Cause Them to Malfunction and Seriously Jeopardize Patient Health and Safety 35

a. Siemens' Knowledge Concerning the Inability of Its "Shippers" to Maintain the Required Temperature Ranges of Refrigerated and Frozen IVDs During the Distribution Process 38

i. Siemens' Testing at ISC Labs 39

ii. Siemens' Testing at BioConvergence 39

b. The representative Cardiac Troponin IVD and Siemens' Admissions Concerning the Public Health Risks of Using "Shippers" That Do Not Maintain IVDs Within Required Temperature Ranges 46

i. Admissions Concerning the Malfunctioning of The Cardiac Troponin IVD When Exposed to Non-Compliant Temperature Conditions Outside FDA-Approved Ranges 46

ii. Admissions concerning the Public Health Risks Associated with Using Unqualified Shippers to Transport Siemens IVDs 55

c. Siemens' Admissions That it Was Sacrificing Patient Safety for Savings on Product Distribution Costs 59

C. Siemens' Misconduct Caused Massive Losses to the Government By Inducing Federal Health Care Programs to Reimburse Claims Based on the Use of Unreliable and Functionally Compromised IVDs That Were Neither FDA-Compliant Nor Medically Necessary, and By Inducing Government Agencies to Pay For Such Medical Devices In Material Breach of Contracting Requirements 62

Plaintiff-relator Mary Bixler Wood ("Relator"), through her attorneys of record, on behalf of the United States of America and the State Plaintiffs, for her Complaint against Defendants Siemens Medical Solutions USA, Inc., Siemens Healthcare Diagnostics, Inc., and Siemens Healthcare Diagnostics Products GmbH (collectively, "Siemens"), alleges as follows:

I. NATURE OF THE ACTION

1. This is a lawsuit to recover damages and penalties on behalf of the United States of America and certain States under the federal and various state False Claims Act statutes. The basis for the lawsuit arises from Siemens' actions in knowingly marketing and distributing in vitro diagnostic ("IVD") medical devices in violation of federal legal requirements designed to assure the devices' safety and efficacy, and under conditions making the IVDs unreliable, rendering the IVDs non-payable by Federal Health Care Programs and the government agencies with which Siemens contracted directly.

2. IVDs, as described by the U.S. Food & Drug Administration ("FDA") on its website, are tests (frequently referred to as assays) which are performed on blood, saliva or tissue samples that "can be used to monitor a person's overall health to help cure, treat or prevent diseases" as well as "to identify patients who are likely to benefit from specific treatments or therapies." *See also* 21 C.F.R. § 809.3(a) (IVDs are "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease"); Pew Charitable Trusts, Issue Brief, "What are In Vitro Diagnostic Tests, and How Are They Regulated?" (May 2019) (IVDs "are used to analyze human samples such as blood and saliva, either by measuring the concentration of specific substances, or analytes (such as sodium and cholesterol), or by detecting the presence or absence of a particular marker or set of markers, such as a genetic mutation or an immune response to infection").

3. IVDs are indispensable to the practice of medicine, as they test for all manner of human medical conditions, including, for example, whether a person is infected with the novel coronavirus that causes the respiratory disease now known around the globe as COVID-19. *See* Bulletin of the World Health Organization, "A Guide to Aid the Selection of Diagnostic Tests" (2017) (IVDs are "indispensable for diagnosing and monitoring disease, for providing prognoses and for predicting treatment responses"). Given the critical diagnostic purposes of IVDs, accuracy and reliability are essential characteristics of these tests. Pew, *supra* ("Patients may receive—or forgo—medical care based on diagnostic test results, ***making it critically important that tests are reliable.***") (emphasis added); Clinical Infectious Diseases, "The Manufacturers' Perspective on World Health Organization Prequalification of In Vitro Diagnostics" (Oxford University Press, Aug. 2017) (promoting global health requires "quality-assured," "reliable" and "robust" IVDs); *see also* World Health Organization, *supra* (discussing need to assess an IVD's accuracy and performance in clinical use and noting there is often limited data "on a test's performance and on whether the manufacturing process is reliable enough to ensure consistent quality across multiple lots"). An IVD that cannot be relied upon to provide an accurate measurement pertaining to the very medical issue for which the test has been designed is, by definition, a materially defective product for which neither payment nor reimbursement may be required under law or contract.

4. Siemens offers a large menu of IVDs to test for a wide array of medical conditions, including a Cardiac Troponin assay, which detects the rise or fall of a key biomarker for myocardial infarction (i.e., heart attack); assays to detect a range of infectious diseases, such as HIV, Zika virus, Rubella, Syphilis, Toxoplasma, Herpes Simplex virus and Epstein-Barr virus; assays used to diagnose thyroid disorders; assays used to diagnose and/or manage conditions like sepsis, diabetes and cancer; assays related to reproductive endocrinology; and assays related to bone metabolism and calcium regulation in the body, including parathyroid hormone assays. Many of these IVD medical

devices are temperature-sensitive and, in many cases, must be maintained in a refrigerated or frozen condition until they are used. Indeed, the critical need for temperature control is a common feature of many medical products, including not just IVDs but also vaccines, as President Joseph Biden has repeatedly emphasized. In a speech on development of coronavirus vaccines that was delivered on September 16, 2020, then-Presidential candidate Biden commented that the vaccines under development for COVID-19 would require "specific means and mechanisms for shipping and storing vaccines at appropriate temperatures," noting that some of the vaccines under development would need to be "shipped and stored at 70 degrees below zero."

5. As further detailed below, Siemens knowingly shipped its customers IVDs (as well as calibrators and controls required to ensure that the IVDs performed in conformity with device specifications approved by FDA and listed by Siemens on the product labels) under non-compliant temperature conditions in order to save costs that it would have otherwise incurred in shipping the IVDs within appropriate validated thermal packaging. This not only violated provisions of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and associated regulations prohibiting the marketing of misbranded and adulterated medical devices, but also compromised the integrity of the Siemens IVDs by degrading the reagents and other materials comprising the IVDs that are utilized in the laboratory testing process. This, in turn, introduced test performance risks and deficiencies that would never have existed if those IVDs had been shipped in a manner consistent with their FDA-approved design and performance specifications, as required by Siemens' own internal policies (*see, infra* ¶ 88).

6. That Siemens engaged in this misconduct, and the damaging impact it had on the efficacy of the IVD products Siemens marketed to customers, including federal and state governments ("the Government"), are established through Siemens' own admissions, in the form of

oral and written statements contained within internal business records and recordings of conversations with Siemens' personnel.

7. An IVD's value in accurately measuring and detecting analytes or markers in the human body obviously cannot be maintained if the temperature conditions necessary to meet the IVD's design and performance specifications do not exist. Siemens, by willfully shipping IVDs outside the temperature conditions necessary to ensure reliable and accurate test performance, knowingly corrupted the design and performance specifications of its own IVD products in ways that destroyed the assurances of testing accuracy and reliability so essential to any IVD product. Siemens' misconduct, in violation of federal laws regulating medical devices, rendered the IVDs unreliable as diagnostic tools, and yet Siemens persisted in marketing the IVDs to Government payers and others without disclosing its misconduct or the compromised conditions of its assays.

8. Siemens caused the Government to spend many millions of taxpayer dollars purchasing these devices, reimbursing purchases of these devices, and reimbursing procedures using these devices, in violation of the federal and state False Claims Acts. A large number of these devices, along with millions of procedures using those devices, have been paid for by Federal Health Care Programs, such as Medicare, TRICARE, and CHAMPVA, as well as the Medicaid program jointly administered by the federal government and the States. Federal and state entities also have been directly purchasing these compromised and unreliable medical devices. The Government thus has been unwittingly bankrolling the purchase and use of these risky IVDs in violation of the Government's own payment terms. This lawsuit seeks to hold Siemens responsible for wrongfully causing this expenditure of public funds, while knowingly risking public health and elevating profits over patient safety.

9. Relator seeks to recover damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-3733, and analogous state statutes, on behalf of the United States of America (the "United

States") and the States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively, the "State Plaintiffs)" against Siemens.

II. PARTIES

10. Plaintiff-Relator Mary Bixler Wood was first exposed to Siemens as a Director of Compliance for a Siemens contractor that performed special projects for Siemens, including a project designed to qualify the shipping containers used by Siemens to maintain the temperature requirements during transport of the medical devices. Relator was in that role from May 2014 to December 2015. Thereafter, Relator served as a contract employee directly for Siemens as a Project Manager for implementation and management of cold chain transportation processes. Her contract term began on February 17, 2016 and ended on April 29, 2016. In both these roles, Relator had access to evidence, gleaned from internal business records and personal interactions with senior Siemens personnel, supporting the allegations made herein.

11. Defendant Siemens Medical Solutions USA, Inc. is a Delaware corporation that conducts business in Malvern, Pennsylvania, and is the parent of defendant Siemens Healthcare Diagnostics, Inc. Siemens Medical Solutions USA, Inc. operates the Americas Distribution Center ("ADC") in Plainfield, Indiana (from where all domestic Siemens IVD shipments originate), and was directly responsible for the wrongful acts and omissions described in this Complaint.

12. Siemens Healthcare Diagnostics, Inc. is a California corporation that conducts business in Tarrytown, New York and is a wholly owned subsidiary of Siemens Medical Solutions USA, Inc. Upon information and belief, Siemens Healthcare Diagnostics, Inc. is responsible for maintaining premarket approvals and 510(k) clearances for the medical devices relevant to this

Complaint, as well as for maintaining compliance with applicable regulatory controls, such as FDA's Quality System Regulations, relating to those devices. Siemens Healthcare Diagnostics, Inc. is also responsible for contracting with the ADC shippers and/or shipper testing companies.

13. Siemens Healthcare Diagnostics Products GmbH is a German corporation with its principal place of business in Marburg, Germany, and is a corporate affiliate of defendant Siemens Healthcare Diagnostics, Inc. Siemens Healthcare Diagnostics Products GmbH manufactures healthcare diagnosis and monitoring equipment. Siemens Healthcare Diagnostics Products GmbH has oversight of quality issues at other corporate affiliates, including quality issues relating to the shipping and storage of devices from the ADC in Plainfield, Indiana. Siemens Healthcare Diagnostics Products GmbH failed in the exercise of such oversight by permitting the wrongful acts described in this Complaint.

III. JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

15. Relator is the original source of the facts and information alleged in this Complaint. Relator voluntarily provided the information on which her allegations are based to the government before filing this action. That information, which Relator obtained by virtue of her prior work for Siemens and a Siemens contractor, was never publicly disclosed within the meaning of 31 U.S.C. § 3730(e)(4)(A) and demonstrates that Siemens sold millions of IVDs used to test for a range of serious medical conditions that Siemens knew did not comply with regulatory requirements prescribing the maximum and minimum temperatures at which such sensitive diagnostic testing devices could be

properly stored and shipped without corrupting product integrity, reliability and accuracy. Siemens knowingly sold adulterated and unreliable IVDs directly to government agencies such as the U.S. Department of Veterans Affairs ("the VA") and U.S. Department of Defense ("the DOD"), and caused claims based on the use of such IVDs to be submitted for reimbursement to Federal Health Care Programs, all without disclosing Siemens' gross non-compliance with regulatory requirements and the consequent unreliability of the IVDs.

16. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), because that section authorizes nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found in this District and/or transact business in this District, and multiple acts constituting violations of 31 U.S.C. § 3729, as alleged herein, occurred in this District.

17. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a), because Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District and/or can otherwise be found and reside in this District. In addition, multiple acts constituting violations of 31 U.S.C. § 3729, as alleged herein, occurred in this District.

IV. APPLICABLE LAW

A. The False Claims Acts

18. The FCA was originally enacted during the Civil War and was substantially amended in 1986. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the

information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

19. The FCA prohibits knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1)(A). Additionally, it prohibits knowingly making or using a false or fraudulent record or statement "material to a false or fraudulent claim" paid or approved by the federal government, or "material to an obligation to pay" money to the government and further prohibits knowingly concealing and improperly avoiding or decreasing "an obligation to pay" money to the government. 31 U.S.C. § 3729(a)(1)(B), (G). Under the FCA, "knowingly" means with "actual knowledge" or "deliberate ignorance" or "reckless disregard" of the truth or falsity of information. 31 U.S.C. § 3729(b)(1). Furthermore, a defendant that does not submit a request for payment directly to the federal government may nonetheless render another party's submission unwittingly false and be held liable for causing the false claim submitted by that other party.

20. Both affirmative misrepresentations and the omission of facts material to a Governmental decision to pay can render a claim false under the FCA. Specifically, the failure to disclose non-compliance with a contractual, statutory or regulatory requirement that is material to the Government's decision to pay a claim for items and/or services, and that renders such a claim misleading as a consequence, is actionable under the FCA pursuant to an implied false certification theory. *See Universal Health Services v. United States et al. ex rel. Escobar et al.*, 136 S. Ct. 1989 (2016). Whether a requirement is material to a payment decision is generally a fact-based inquiry, and considers the effect of a misrepresentation regarding compliance on the likely or actual behavior of one who receives the misrepresentation, as well as such factors as whether the Government has expressly designated the violated requirement to be a condition of payment and/or whether the

requirement is central to a Government program or otherwise goes to the very essence of the bargain. *Id.* at 1995, 2001 and n.5, 2003-04.

21. The FCA also prohibits two or more parties from conspiring to violate any of the liability provisions of the statute. 31 U.S.C. § 3729(a)(1)(C). Any person who violates, or conspires to violate, the FCA is liable for a civil penalty of up to $11,000 per claim for claims made on or after September 29, 1999 (and up to $23,331 per claim for claims made after November 2, 2015), plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a).

22. The FCA does not require direct contact between a Defendant and the government. By its terms, the FCA imposes liability on any person who presents or ***causes*** to be presented a false or fraudulent claim to the government (or false statement in support of a false or fraudulent claim). See 31 U.S.C. § 3729(a).

23. To "cause" an FCA violation, it is not necessary that a Defendant's fraudulent conduct be the last in the series of events that results in financial loss to the government. As applied by the courts, the standard for "causation" under the FCA is whether the submission of a false or fraudulent claim was "reasonably foreseeable" from a Defendant's actions. Under this standard, a Defendant's fraudulent conduct can occur anywhere in the chain of events leading to financial loss by the government, and can be an indirect, as well as direct, cause of the loss. Moreover, the Defendant need not be the recipient or beneficiary of the false claim. All that is required is that the Defendant, by its fraudulent conduct, set in motion a series of events which results in a reasonably foreseeable loss to the government.

24. The FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property which is requested or

demanded, or if the government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

25. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendants during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

26. The State Plaintiffs have false claims acts that are modeled after the federal statute, and that permit recovery for the fraudulent misconduct described herein, which caused losses to state Medicaid programs and state agencies that purchased Siemens IVD products. The state statutes generally permit doubling or trebling of loss amounts, and impose various civil penalty amounts.

B. Regulatory Background Relating to Medical Devices

27. The FDCA governs, among other things, the manufacturing and marketing of medical devices within the United States, requiring that medical devices possess a reasonable assurance of safety and effectiveness for their intended uses. The FDA regulates medical devices under the FDCA to protect consumers from medical devices that are unsafe or ineffective. The FDA's medical device regulations, along with other regulations specific to IVDs, regulate the manufacture, marketing, and distribution of IVDs, in addition to other requirements specific to IVDs.

28. To protect public health, the FDCA prohibits, among other things: (i) the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded medical device 21 U.S.C. § 331(a); (ii) the adulteration or misbranding of medical devices while they are in interstate commerce, 21 U.S.C. § 331(b); (iii) the receipt in interstate commerce of any adulterated or misbranded medical device, 21 U.S.C. § 331(c); and (iv) ***the delivery or proffered delivery thereof for pay or otherwise of any adulterated or misbranded medical device***, 21

U.S.C. § 331(c) (emphasis added). The FDCA also prohibits the failure to comply with certain post-marketing reporting obligations. 21 U.S.C. § 331(q). Violating any of these statutory mandates is a crime pursuant to 21 U.S.C. § 333(a).

a. **FDA Approval and Clearance of Medical Devices Under the FDCA**

29. Federal law grants FDA the authority and responsibility to monitor medical devices intended to be marketed within the United States to ensure that the devices are reasonably safe and effective.

30. Among other things, federal law requires medical device manufacturers to obtain FDA premarket approval or clearance before certain medical devices may be commercially distributed within the United States. FDA requires these approval and clearance processes for higher-risk medical devices to provide reasonable assurances of their safety and efficacy.

31. Federal law classifies medical devices into three classes of increasing regulatory scrutiny based on the purpose they are intended to serve and the risk to health they present: Classes I, II, and III.

32. Medical device manufacturers must obtain FDA premarket approval ("PMA") before commercially distributing Class III devices in the United States. Class III devices are the highest-risk devices and support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

33. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

34. PMA is the most stringent type of device marketing application required by FDA. After FDA has approved a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making any change affecting the safety or effectiveness of the device. The types of changes that require a PMA supplement, if such changes affect the safety or

effectiveness of the device, include, but are not limited to, labeling changes, changes in packaging, storage temperature changes and extension of the expiration date of the device based on data obtained under a new or revised shelf-life testing protocol that has not been approved by FDA. 21 C.F.R. § 814.39(a).

35. The FDCA defines different types of PMA supplements that are used to request approval of a change to a device that has an approved PMA: 180-day supplements, real-time supplements, panel-track supplements. A "real-time supplement" is a request for a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement. 21 U.S.C. § 379i(4)(D).

36. A PMA "real-time supplement" is generally required for changes in the upper and lower limits of storage temperatures for medical devices. *See* FDA, Center for Devices and Radiological Health ("CDRH"), "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision" (Dec. 11, 2008). Alternatively, FDA as part of a PMA approval order may approve a stability testing protocol, which allows the manufacturer to change temperature requirements and shelf-life requirements without a "real time supplement" if testing is performed pursuant to the approved protocol.

37. For Class III PMA-approved devices, manufacturers must obtain FDA permission to change temperature ranges through a PMA supplement. *See* FDA Guidance, Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process (Dec. 11, 2008) (PMA Supplement Guidance), at 16 (noting that a supplement would be sufficient to raise storage temperature by 5 degrees, where "[s]tability data at the new higher temperature was sufficient to support [the] change and was conducted using an accepted test method"). For 510(k)-

cleared devices, if significant changes in packaging, shipping, or shelf life mean that the devices do not "continue[] to conform to performance specifications," manufacturers must file an altogether new 510(k) submission. *See* FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device, (Jan. 10, 1997), at 16; *see also* FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device (Draft Guidance) (Aug. 8, 2016).

38. Any device requiring, but lacking PMA approval, is both adulterated and misbranded, and marketing such a device is also a prohibited act under federal law. See 21 U.S.C. § 331(p), 351(f).

39. Class II devices are those FDA has determined to present a moderate to high risk and, unless specifically exempted, require marketing clearance from FDA before they may be lawfully distributed in the United States. In addition, some Class I (low risk) devices are also subject to this requirement. The marketing clearance process is generally referred to as the 510(k) clearance process, because the process is dictated by section 510(k) of the FDCA.
Federal law requires 510(k) clearance in a number of circumstances.

40. In particular, a manufacturer must seek 510(k) clearance from FDA before introducing a relevant device into interstate commerce for the first time; before marketing a change or modification to an already cleared device that "could significantly affect safety or effectiveness;" or before marketing a major change or modification to the intended use of a previously 510(k)-cleared device. See 21 C.F.R. § 807.81(a); see also, 21 U.S.C. § 360(k). By ignoring the 510(k) clearance requirement, a manufacturer deprives FDA of the ability to assess whether a device is substantially equivalent to a lawfully marketed predicate device that FDA uses as a measure of the relative safety and efficacy of the new, or newly modified, device.

41. FDA requires the submission of a new premarket clearance submission when changes to an existing device, including but not limited to changes in temperature storage limits,

"could significantly affect the safety or effectiveness of the device." 21 C.F.R. § 807.81(a)(3). FDA guidance on "Deciding When to Submit a 510(k) for a Change to an Existing Device" provides that "a change in device packaging or expiration dating" may require a new premarket clearance if such test methods or protocols, not described in the original premarket notification, are used to support a change in package integrity or shelf-life claims.

42. Any device requiring, but lacking, 510(k) clearance is both adulterated and misbranded, and marketing such a device is also a prohibited act under federal law. See 21 U.S.C. § 331(p), 351(f).

b. FDA Quality System Regulations Ensure Compliance With Current Good Manufacturing Practices

43. Federal law requires medical device manufacturers to design, produce, package, label, evaluate, and monitor devices in accordance with current good manufacturing practices ("cGMP') to ensure that the medical devices are reasonably safe and effective. These cGMP requirements for devices marketed in the United States are codified in FDA's Quality System Regulation (the "QSR"). See 21 C.F.R. Part 820.

44. The QSR generally governs any entity that designs, manufactures, fabricates, assembles, or processes a finished device (*i.e.*, a device that is capable of functioning, whether or not it has been packaged, labeled, or sterilized), as well as any entity that performs the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions. 21 U.S.C.§ 820.3(o).

45. QSR requirements include requirements, among others, governing design controls, purchasing controls, production and process controls, process validation, document controls, acceptance activity controls, nonconforming product controls, device master records,

complaint handling procedures, processes for corrective and preventive actions, the establishment of quality plans, procedures for and the conduct of quality audits, and handling, storage, and distribution controls.

46. One QSR requirement is design validation. Validation should address, among other things, product packaging and labeling and include simulation of the expected environmental conditions, such as temperature, humidity, shock and vibration, and corrosive atmospheres. See FDA, CDRH, "Design Control Guidance for Medical Device Manufacturers" (Mar. 11, 1997) at p. 34. Among other things, environmental stresses encountered during shipment of a medical device should be addressed during the validation process since such stresses may "far exceed those encountered during actual use." Id. at p. 35; *see also* 21 C.F.R. § 820.30(g). Design control requirements apply to all Class II and III devices, and most Class I devices. 21 C.F.R. §820.30(a)(1).

47. QSR requirements mandate that manufacturers establish and maintain procedures that ensure damage, deterioration, contamination, or other adverse effects to product do not occur during handling, in storage areas, during distribution and to ensure deteriorated products are not used or distributed.

48. Specifically, regulations require that each manufacturer "establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling." 21 C.F.R. § 820.140. Further, the manufacturer must also "establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed." 21 C.F.R. § 820.150. When, as in the case of temperature-sensitive IVDs having a defined shelf life, the quality of a product deteriorates over time, "it shall be stored in a manner to

facilitate proper stock rotation, and its condition shall be assessed as appropriate." Id.

49. Moreover, each manufacturer is required to "establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed" and that "[w]here a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed." 21 C.F.R. § 820.150.

50. A medical device that is not manufactured in conformity with applicable QSR requirements is considered adulterated by FDA and cannot be lawfully marketed in the United States. *See* 21 U.S.C. § 351(h). This includes any medical device that is not manufactured, packed, stored or installed in conformity with cGMP. 21 U.S.C. § 351(h).

51. By ignoring applicable QSR validation and other quality control requirements a manufacturer risks producing medical devices that lack any reasonable assurance of safety and efficacy. In the case of IVDs, this means assays that cannot be safely relied upon to produce accurate measurements that are essential for appropriate medical decision-making concerning such matters as whether and/or when to receive life-saving medical treatment.

c. Medical Device Labeling

52. Federal law governs the content, format, truthfulness, and completeness of medical device labeling to ensure, among other things, that medical device users are not deceived and to protect the public from unsafe or ineffective device use and against safety and efficacy problems arising from, among other things, the inadvertent misuse or overuse of such devices. A medical device is misbranded if its labeling is "false or misleading in any particular" or if it lacks sufficient information for use, including adequate instructions regarding how to use devices (*e.g.*, information about shelf life), as well as adequate warnings relevant to device use. *See* 21 U.S.C. §§ 352(a), (f); *see generally* 21 C.F.R., Part 801.

53. IVD reagents are specifically required to provide labeling with appropriate storage instructions adequate to protect the stability of the products, including such information as the conditions of temperature under which it must be stored. Such conditions of temperature are to be based upon reliable, meaningful, and specific test methods. 21 C.F.R. § 809.10(a)(5). FDA regulations also require that "the basis of such instructions [to protect the stability of the product] shall be determined by reliable, meaningful, and specific test methods such as those described in [21 CFR § 211.166]," an FDA regulation requiring a written stability testing program in order to establish "appropriate storage conditions and expiration dates." 21 C.F.R. §§ 211.166, 809.10(a)(5).

54. Likewise, the labeling of IVD reagents is also required to include "a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use," including an expiration date indicating the reagent's useful life, which is based upon the storage conditions stated in the labeling, including temperature conditions. 21 C.F.R. § 809.10(a)(6)(i).

55. By ignoring labeling requirements, a manufacturer may deceive or mislead users and may cause the unsafe or ineffective use, misuse, or overuse of a medical device, rendering the device neither reasonably safe nor effective.

56. A manufacturer's violation of FDA labeling requirements renders a device misbranded under the FDCA. See 21 U.S.C. § 352; 21 C.F.R., Part 801.

C. Government Payments for IVDs

a. Federal Health Care Programs

57. The health care programs described in the paragraphs below, and any other government-funded healthcare programs, shall be referred to as "Federal Health Care Programs."

i. Medicare

58. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare") is a health insurance program administered by the United States that is funded by taxpayer revenue. Entitlement to Medicare is based on age, disability or affliction with certain diseases. The program is overseen by the United States Department of Health and Human Services ("HHS") through the Centers for Medicare and Medicaid Services ("CMS"). Medicare provides for the payment of hospital services, durable medical equipment and medical services, including diagnostic laboratory testing. Pursuant to Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D extended prescription drug coverage to all Medicare-eligible persons who choose to participate in the Part D program.

59. Medicare rules govern the reimbursement of medical services and supplies, including medical devices like IVDs and services using such devices. As relevant here, Medicare benefits cover only items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A). The use of an adulterated and/or misbranded IVD that cannot reliably provide accurate measurements in conformity with its design and performance specifications due to non-compliant temperature fluctuations or excursions during shipping and handling, in violation of federal QSR requirements, cannot be "reasonable and necessary" for diagnosis or treatment, and thus is non-reimbursable by statute. Due to the manufacturer's violation of federal quality standards, use of the device carries no assurances of reliability, safety or efficacy, and thus neither the device nor the service may be deemed "reasonable and necessary" in any respect. "Reasonable and necessary" cannot and does not mean that Medicare is obligated to forfeit the very protections and assurances of reliability that the FDA QSR requirements bestow by paying for misbranded and adulterated devices or the services they are used to provide. Nor can it be "reasonable and necessary" for Medicare to ***pay*** for the very same misbranded and adulterated

devices that manufacturers are statutorily barred from ***selling*** pursuant to 21 U.S.C. § 331(c), which bars Siemens from delivering misbranded and adulterated devices "for pay or otherwise." To the contrary, paying for such devices would directly undermine this statutory mandate, and facilitate Siemens' commission of a crime, *see* 21 U.S.C. § 333(a) (making the violation of § 331(c) a crime), which plainly cannot qualify as "reasonable and necessary."

60. Medicare rules also prohibit reimbursement for the use of a device requiring, but lacking, PMA approval or 510(k) clearance by FDA. For instance, Medicare classifies any medical device that is neither cleared nor approved for marketing by FDA as "investigational." See 42 C.F.R. § 411.15(o). Federal law prohibits Medicare reimbursements "for any expenses incurred for items or services" relating to care and services using investigational devices, except for certain clinical trials. See 42 U.S.C. § 1395y(a)(1)(D); see also 42 C.F.R. § 411.15(o).

ii. <u>Medicaid</u>

61. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v ("Medicaid") is a health insurance program administered by the United States and individual states and is funded by federal and state taxpayer revenue. The Medicaid Program is overseen by HHS through CMS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid. Diagnostic laboratory testing is included among the many kinds of medical services which are covered under state Medicaid programs.

62. Medicaid rules govern the reimbursement of medical services and supplies, including medical devices like IVDs and services using such devices. Pursuant to both federal and state Medicaid reimbursement rules, Medicaid benefits cover only items and services that are medically necessary. 42 U.S.C. § 1396-1, 1396d(r). The Medicaid programs of the State Plaintiffs variously require as conditions of reimbursement that procedures and services be "medically necessary" or a

"medical necessity," or prohibit reimbursement for procedures and services that are "unnecessary" or that do not meet professional standards of appropriateness. In certain jurisdictions, program rules condition reimbursement on compliance with federal laws, including the adulteration and misbranding provisions of the FDCA. Under all of these rules, Medicaid would deny reimbursement for the use of medical devices that are not FDA-approved or -cleared and/or that do not comply with FDA safety and quality regulations.

63. The use of an adulterated or misbranded IVD that cannot reliably provide accurate measurements in conformity with its design and performance specifications due to non-compliant temperature fluctuations or excursions during shipping and handling, in violation of federal QSR requirements, cannot be medically necessary or professionally appropriate for diagnosis or treatment, and thus is non-reimbursable. Due to the manufacturer's violation of federal quality standards, use of the device carries no assurances of reliability, safety or efficacy, and thus neither the device nor the service may be deemed medically necessary or appropriate in any respect. "Medically necessary" and "professionally appropriate" cannot and do not mean that Medicaid is obligated to forfeit the very protections and assurances of reliability that the FDA QSR requirements bestow by paying for misbranded and adulterated devices, and the services they are used to provide. Nor can it be "medically necessary" or "professionally appropriate" for Medicaid to ***pay*** for the very same misbranded and adulterated devices that manufacturers are statutorily barred from ***selling*** pursuant to 21 U.S.C. § 331(c), which bars Siemens from delivering misbranded and adulterated devices "for pay or otherwise." To the contrary, paying for such devices would directly undermine this statutory mandate, and facilitate Siemens' commission of a crime, *see* 21 U.S.C. § 333(a) (making the violation of § 331(c) a crime), which is neither "medically necessary" nor "professionally appropriate."

iii. TRICARE (formerly CHAMPUS)

64. The federal health care program for the United States military (formerly known as the Civilian Health and Medical Program of the Uniformed Services or CHAMPUS, and now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians and suppliers to active-duty service members and retirees of the seven uniformed services: Army, Marine Corps, Navy, Air Force, Coast Guard, Commissioned Corps of the Public Health Service and the Commissioned Corps of the National Oceanic and Atmospheric Association. TRICARE is also available to immediate family members and survivors of military personnel. The program is administered by the Department of Defense and funded by the federal government. Among other things, this program pays for diagnostic laboratory testing for its beneficiaries.

65. TRICARE rules govern the reimbursement of medical services and supplies, including medical devices like IVDs and services using such devices. TRICARE benefits cover only "medically or psychologically necessary services and supplies required in the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(i).

66. The use of an adulterated or misbranded IVD that cannot reliably provide accurate measurements in conformity with its design and performance specifications due to non-compliant temperature fluctuations or excursions during shipping and handling, in violation of federal QSR requirements, cannot be medically necessary for diagnosis and treatment, and thus is non-reimbursable. Due to the manufacturer's violation of federal quality standards, use of the device carries no assurances of reliability, safety or efficacy, and thus neither the device nor the service may reasonably be deemed "medically necessary" in any respect. "Medically necessary" cannot and does not mean that TRICARE is obligated to forfeit the very protections and assurances of reliability that the FDA QSR requirements bestow by paying for misbranded and adulterated

devices, and the services they are used to provide. Nor can it be "medically necessary" for TRICARE to ***pay*** for the very same misbranded and adulterated devices that manufacturers are statutorily barred from ***selling*** pursuant to 21 U.S.C. § 331(c), which bars Siemens from delivering misbranded and adulterated devices "for pay or otherwise." To the contrary, paying for such devices would directly undermine this statutory mandate, and facilitate Siemens' commission of a crime, *see* 21 U.S.C. § 333(a) (making the violation of § 331(c) a crime), which plainly cannot qualify as "medically necessary."

67. TRICARE rules also prohibit reimbursement for the use of a device requiring, but lacking, PMA approval or 510(k) clearance by FDA. For instance, TRICARE classifies any medical devices that are neither cleared nor approved for marketing by FDA as unproven and investigational. See 32 C.F.R. § 199.4(g)(15); TRICARE Policy Manual (2008), Chap. 8, § 5.1. Except in certain clinical trials, TRICARE rules prohibit payment for any "device, medical treatment or procedure" relating to a device or the use of a device that is unproven, including "all services directly related to the unproven . . . device." See 32 C.F.R. § 199.4(g)(15); TRICARE Policy Manual (2008), Chap. 8, § 5.11.

iv. <u>CHAMPVA</u>

68. The federal government, through the U.S. Department Veterans Affairs, maintains and operates medical facilities, including hospitals, and receives and uses federal funds to provide for health care coverage and purchase medically necessary prescription drugs and medical devices for patients treated at such facilities and otherwise. The program, known as the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), benefits certain veterans, as well as the spouses and children of certain veterans. See 38 U.S.C. § 1781; 38 C.F.R. § 17.270, et seq.

69. CHAMPVA rules govern the reimbursement of medical services and supplies,

including medical devices like IVDs and services using such devices. CHAMPVA benefits cover only "allowable expenses for medical services and supplies that are medically necessary and appropriate for the treatment of a condition" 38 C.F.R. § 17.272(a).

70. The use of an adulterated or misbranded IVD that cannot reliably provide accurate measurements in conformity with its design and performance specifications due to non-compliant temperature fluctuations or excursions during shipping and handling, in violation of federal QSR requirements, cannot be "medically necessary and appropriate" for reimbursement purposes. Due to the manufacturer's violation of federal quality standards, use of the device carries no assurances of reliability, safety or efficacy, and thus neither the device nor the service may reasonably be deemed "medically necessary and appropriate" in any respect. Needless to say, "medically necessary and appropriate" cannot and does not mean that CHAMPVA is obligated to forfeit the very protections and assurances of reliability that the FDA QSR requirements bestow by paying for misbranded and adulterated devices, and the services they are used to provide.

b. <u>Federal and State Purchasers of Medical Devices</u>

71. On information and belief, federal and state procurement policies and contracts require that purchased medical devices, including the IVDs marketed by Siemens, comply with federal laws mandating that medical devices comply with QSR regulations, that medical devices be approved or cleared as appropriate, and that medical devices are not otherwise adulterated or misbranded.

72. For instance, vendors doing business with the VA must complete a vendor response form which states:

> **FDA Regulatory Requirements**
> Offerors of products classified as medical devices by the U.S. Food and Drug Administration shall be in compliance with the Federal Food Drug and Cosmetic (FD&C) Act, as amended, and

> regulations promulgated there under (codified in 21 CFR Parts 800-1299). ***Offerors of medical devices not in compliance with these regulations shall not be considered for award under this solicitation.***

Vendor Response Document, RFP-797-FSS-99-0025-R10 (emphasis added), attached hereto as Exhibit 48. Solicitations on behalf of DOD include extensive FDA compliance requirements, including that the proposal "include documentation that demonstrates that the manufacturer has complied with all applicable FDA regulations." DOD Solicitation Document, attached hereto as Exhibit 49.

73. Likewise, the DOD, pursuant to a Memorandum of Understanding with FDA, includes a provision in all its contracts for medical products "requiring compliance with the [FDCA] and implementing regulations promulgated thereunder" and further requiring that "FDA's current Good Manufacturing Practice Regulations, when applicable . . . be incorporated into these contracts [as] the quality standard for the manufacturing, processing, packaging or holding of medical products acquired by government contracts." Memorandum of Understanding Between Defense Logistics Agency and Food and Drug Administration, MOU 225-15-016, Section 6, Administration (2015), attached hereto as Exhibit 50. Indeed, a very recent IVD contract between Siemens and the Department of the Navy, totaling almost $1.8 million, contains extensive requirements for FDA compliance, providing, among other things: (a) that "the manufacturer shall adhere to good manufacturing processes in the manufacture of the devices"; (b) that if the manufacturer seeks to modify the IVD specifications, it must demonstrate "that the manufacturer has complied with all applicable FDA regulations, including those concerning the filing of a new 501K notice if such action and subsequent FDA clearance are warranted by the nature of the modification"; (c) that the package insert for the device must contain information needed to ensure that the device can be used "consistent with" and to "derive the full benefit of"

its FDA approval; (d) that the device "shall meet all contract specifications to the end of expiration date"; and (e) ***that the manufacturer "will ship biologic reagent items used in the reagent kits in insulated thermal containers to ensure protection of the reagents against thermal (Heat/Cold) damage which would affect reagent performance."*** (emphasis added). *See* Contract No. 11626451905017, signed September 20, 2019, attached hereto as Exhibit 47. Moreover, Siemens' own risk assessment for this IVD product, an EMIT test commonly used for drug screening, shows that storing or shipping the product, which must be refrigerated, in non-compliant temperature conditions is associated with risk of patient harm. *See* FMEA Spreadsheet Excerpts, attached hereto as Exhibit 10F.

74. On information and belief, all federal and state agencies purchasing medical devices incorporate requirements into their purchasing contracts that are substantially similar to the FDA compliance requirements imposed by the VA and DOD. None of these agencies would enter into an IVD purchasing contract if the agency knew in advance that the vendor's products would not be in compliance with FDA requirements. Siemens' undisclosed sale of adulterated and misbranded medical devices thus constituted both a violation of the express payment terms of these contracts, and also a fraudulent inducement of Government agencies to purchase Siemens' IVD products.

75. In addition to the express contractual requirements imposed by government agencies, it is an assumed and material element of any contract for the purchase of an IVD that the IVD will be reliable, safe and effective and ***not*** be misbranded or adulterated at the time of delivery. It would subvert the purpose of the contract and violate the implied covenant of good faith and fair dealing in every contract for the seller to secretly deliver to the buyer an IVD not meeting these requirements. Indeed, it would violate a contract requirement going to the very essence of the bargain, as well as a ***statutory requirement*** expressly prohibiting and making

criminal the "the delivery or proffered delivery thereof for pay or otherwise of any adulterated or misbranded medical device." 21 U.S.C. §§ 331(c), 333(a). Thus, the sale of an adulterated or misbranded IVD that cannot reliably provide accurate measurements in conformity with its design and performance specifications due to non-compliant temperature fluctuations or excursions during shipping and handling, in violation of federal QSR requirements, indisputably constitutes a material breach of the purchase contract and voids any payment obligation.

c. Federal and State Agencies Pay Claims For Siemens IVDs Through Insurance Reimbursement and Direct Contract Payments

76. Siemens is among the largest IVD manufacturers in the world, with testing products that are utilized in every corner of the healthcare delivery system, from hospitals to clinical laboratories to physician providers. Siemens was the third largest IVD manufacturer globally in 2015. *See* PRNewswire article, "Report: Siemens Healthcare a Refocused IVD Competitor in 2015" (Feb. 12, 2015).

77. Siemens has approximately 13% of the $40-45 billion global IVD market. Roughly 45% of that global market or about $20 billion is right here in the United States. *See* European Observatory on Health Systems and Policies, a partnership hosted by World Health Organization, "Ensuring Innovation in Diagnostics for Bacterial Infection: Implications for Policy," Chapter 3 "Overview of the Diagnostics Market" (2016). Siemens has been called a "major player in laboratory diagnostics" with "products for clinical chemistry, drug testing, hematology, coagulation, immunoassay, infectious diseases, molecular diagnostics, point of care testing and many others." *See* Fortune Business Insights, In Vitro Diagnostics (IVD) Market, Report ID: FBI101443 (online summary) (Sept. 2019). With a "strong product portfolio and supply chain," Siemens is viewed as "dominant in the in vitro diagnostics market." *Id.* In the first quarter of 2020 alone, Siemens generated more than $1 billion in revenues from sales of its

diagnostic products. *See* Siemens Q1 Fiscal Year 2020 Quarterly Statement.

78. It is indisputable that Siemens IVDs are reimbursed by Federal Health Care Programs. Apart from the commonsense inference that it is "highly likely" – indeed inevitable – that claims arising from use of the testing products made by an IVD manufacturing colossus like Siemens "will indeed reach the government insurers," *see United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 85 (2d Cir. 2017), Siemens affirmatively contracts with a third party to provide government reimbursement information for its entire menu of IVDs through an online product called CodeMap, the website for which can be accessed here: www.codemap.com/siemens/userhome.cfm (*See* Exhibit 1, attached hereto). CodeMap names each Siemens IVD system with a hyperlink to a chart that lists the associated tests and CPT codes, explains Medicare coverage and conditions, and provides reimbursement amounts. The CodeMap website expressly directs that any reimbursement questions be forwarded to the email address of Siemens' Senior Director for Policy and Reimbursement.

79. All of these IVDs, and the medical services utilizing them, are reimbursed by Federal Health Care Programs on the assumption that the IVDs are reliable, safe and effective for medically necessary diagnosis and treatment. Although Siemens does not submit the claims itself, Siemens ***causes*** those claims submissions through its nationwide marketing of IVDs to physicians, hospitals and clinical laboratories. Moreover, Siemens knows and fully intends, as demonstrated by its provision of detailed reimbursement information to customers, that medical providers will submit claims seeking government reimbursement for use of Siemens IVD products.

80. Some or all of these IVDs also are purchased directly by government agencies. Indeed, Siemens explicitly acknowledges on its website that it supplies IVDs to DOD and the VA (*see* https://www.siemens-healthineers.com/en-us/about-us/federal-accounts#Contracting).

81. For example, Siemens has a contract with the VA's Medical Equipment Division

for "Laboratory Instruments and Equipment" (*see* Contract No. V797D-30175, attached hereto as Exhibit 2). The contract period stated on the face of the agreement runs from 6/1/13 through 5/31/18, but the VA website states that the contract actually does not expire until 6/30/20 (*see* https://www.vendorportal.ecms.va.gov/NAC/Search/Details/V797D-30175).

82. The VA contract lists all the IVD products subject to the agreement. They include a full array of Siemens IVD systems, including reagents, calibrators and controls. The contract lists each individual Siemens product by "Siemens Material Number" and includes "U.S. Government CPT Pricing" with three different tiers based on either annual revenue or annual number of patient tests. Scores of IVD products on the contract list require shipping and handling in a frozen or refrigerated condition, including, among many others, the Cardiac Troponin assay used for the detection of myocardial infarction (*i.e.* heart attack) and the Intact PTH assay, which is used heavily in the dialysis setting and for patients with seriously compromised kidney function in order to measure parathyroid hormone levels in the bloodstream.

83. Various other agencies have contracted directly with Siemens for IVD products as well, including HHS (a $8,945,785 contract signed in April 2017 for Siemens' Advia Centaur Immunoassay Systems), the Department of the Air Force (a $150,000 contract signed in July 2016 for Siemens' Dimensions EXL 200 testing system and reagents); the Federal Bureau of Prisons (a $14,385.30 contract signed in September 2013 for lab reagents to detect HIV infection) and the Department of the Navy (a $284,702.83 contract signed in November 2008 for Siemens' Cardiac Troponin assay), to name just a few. A non-exhaustive list of other federal agency contracts with Siemens is attached hereto as Exhibit 3.

V. THE FACTS UNDERLYING SIEMENS' DANGEROUS AND FRAUDULENT MISCONDUCT

A. Siemens' Own Stress Testing and Risk Assessments Revealed The Dangers of Exposing IVDs To Temperature Conditions Outside Their FDA-Approved Parameters

a. Stress Testing

84. Many Siemens IVDs (including reagents, as well as calibrators and controls that are used to ensure that the IVDs function properly in a laboratory setting), which are heavily relied upon by physicians, hospitals and clinical laboratories throughout the United States to inform medical decision-making, are highly temperature-sensitive devices that must be maintained in a refrigerated or frozen condition in order to ensure reliability, safety and efficacy in clinical use. The Cardiac Troponin assay used in the diagnosis of acute myocardial infarctions is just one example. Other Siemens IVDs falling into this category are listed in an internal, Siemens-prepared Excel spreadsheet, attached hereto as Exhibit 4.

85. To assess whether its devices may be exposed, even briefly, to various temperature ranges, Siemens conducts "stress testing." These tests expose devices to particular temperatures (*e.g.*, freezing, thawing, or specified warm or hot temperatures) for particular defined intervals, and then test whether the devices still function as designed. If a device fails, the device cannot be exposed to that temperature range for that amount of time. Stress testing is critical for IVDs.

86. Siemens has recognized that IVDs are sensitive to temperature changes, and must be "stored and shipped under specific controlled temperature conditions … to ensure product integrity is maintained throughout the distribution process." Siemens Sept. 11, 2015 Mem., attached hereto as Exhibit 5, at 1 ("In Vitro Diagnostic products (IVDs) must be stored and shipped under specific controlled temperature conditions (frozen, refrigerated or ambient temperatures) to ensure product integrity is maintained throughout the distribution process

(reference … QSR 21 CFR Part 820) … most of the In Vitro Diagnostic Products contains [sic] proteins or enzymes which are very temperature sensitive. In any case the storage and shipping conditions must be selected such that the products maintain their safety and performance.").

87. Siemens' internal policy requires stress testing under various freeze-thaw and Ambient Routine ("AR") conditions. *See* Siemens Global Procedure GP-033, Product Protection for Reagents and Disposables (May 16, 2012) ("GP-033"), attached hereto as Exhibit 6. As the policy clearly states, "products are stored and shipped under specific frozen, refrigerated or ambient temperature conditions to ensure product integrity is maintained throughout the distribution process. The required temperature conditions are established on the basis of stability data obtained during product development, validation, historical performance and/or routine product monitoring." *Id.* at 3. Attachment 4 to the policy details product storage and shipping information for specific products. *See* Excerpts of DQSP-00033-A4, attached hereto as Exhibit 7.

b. Risk Assessments

88. Siemens' stress testing helps determine whether an IVD exposed (in shipping or otherwise) to temperatures beyond its approved or cleared temperature range will still function in conformity with its design and performance specifications. Where stress testing indicates a device may not function appropriately, the next significant question is what level of public health risk that failure presents.

89. With IVDs, the answer is that product failure presents a serious public health risk. Faulty diagnostic tests could result in false-positives or false-negatives, thus causing misdiagnosis. Misdiagnoses are a public health concern that can lead to deferred treatments, unnecessary treatments, death, and serious injuries, among other negative consequences. Siemens documented these serious risks in its own records. In particular, Siemens recorded risk assessments in its Failure Mode and Effects Analyses (FMEAs). The FMEA is an important element of risk management in

design validation, as required by 21 C.F.R. § 20.30(g), which mandates that FMEAs, as the operative risk management files, "include testing of production units under actual or simulated use conditions." 21 C.F.R. § 820.30(g). Siemens' internal policies require that the FMEAs reflect current knowledge. *See* Siemens Risk Management Process, DQSP-00017 (Sept. 14, 2014), attached hereto as Exhibit 8, at 8. Siemens' policies also explain that the typical tool used for risk assessment is the FMEA. *See id.* at 6 ("Typically risk assessment is performed using Failure Mode and Effects Analysis (FMEA)"). According to Siemens' internal policies, "[t]he plan is updated throughout the product development cycle as necessary." *Id.*

90. Relator had access to FMEAs reflecting Siemens's own assessment that IVD product exposure to temperatures beyond those approved or cleared by FDA would present serious public health risks. *See* Excerpts of Troponin FMEA Spreadsheet, attached hereto as Exhibit 9, at row 307. As noted in the FMEA's "Scoring Criteria" tab, the FMEA ranks the severity of potential risks, from negligible to major. Major means "results in death, life-threatening or permanent impairment or injury." *Id.* The "FMEA-Troponin I" tab presents the risk analysis. Column H presents the possible risks or "failure modes." Columns 304 and 305 address what could happen if the kits containing the devices are shipped "at incorrect temperatures." *Id.* According to Siemens, that could lead to either an "elevated erroneous result" or a "depressed erroneous result," with the latter leading to "misdiagnosis or delayed intervention for acute myocardial infarction." Unsurprisingly, Siemens ranked this as having the highest severity level: Major. *See id.*

91. Other FMEAs also exist within Siemens' risk management files assessing the respective risk levels of additional Siemens IVDs if they are being shipped outside their FDA-approved or -cleared temperature ranges. Some of these FMEAs, which also have been personally reviewed by Relator, disclose "likely" "high risk" and "moderate risk" harms resulting from such temperature non-compliance, ranging from possible birth defects, to missed viral infection and

cancer diagnoses to mishandling of dialysis patients for infectious disease during hemodialysis. *See* FMEA Spreadsheet Excerpts, attached hereto as Exhibits 10A through 10F.

B. Siemens Knowingly Shipped Adulterated and Misbranded IVDs Outside FDA-Mandated Temperature Ranges in Order to Save Distribution Costs, Despite Evidence That Doing So Would Cause Them to Malfunction And Seriously Jeopardize Patient Health and Safety

92. As further detailed below, for many years, Siemens has knowingly shipped temperature-sensitive IVDs well outside their FDA-approved or -cleared temperature ranges. Siemens IVD devices are Class II or Class III products. Siemens was required to seek approval or clearance from FDA to ship these IVD devices outside of their previously approved temperature ranges. *See, supra,* at ¶¶ 36-42. Siemens, however, has not sought approval or clearance from FDA to ship its devices in the conditions they experience.

93. Siemens is required to ensure that device packaging and shipping containers are designed and constructed to protect devices from alteration or damage during the customary conditions of storage, handling, and distribution. *See, supra,* at ¶¶ 43-51. Design controls are the checks and balances incorporated into the device design and development process. Design controls establish essential quality requirements, such as the safety, performance and dependability of a product. *See id.*

94. Siemens' shipping containers, shipping conditions, and storage conditions are subject to design control requirements and other QSR requirements mandating that Siemens establish and maintain procedures that ensure damage, deterioration, contamination, or other adverse effects to product do not occur during handling, in storage areas, during distribution and to ensure deteriorated products are not used or distributed. *See, id.* Siemens, however, failed to comply with any of these requirements.

95. The labels on Siemens IVDs include temperature storage requirements and representations about shelf life. Those representations are based on purported testing conducted under the temperature conditions cleared or approved by the FDA. Upon information and belief, Siemens has not conducted stability testing to validate the accuracy of the information on its device labels. *See, supra,* at ¶¶ 53-56. In particular, Siemens has not validated that the shelf life and expiration data on the device labels are accurate under the conditions in which devices are actually stored and shipped. Indeed, upon information and belief, in some instances, Siemens knows that the expiration and shelf-life information on its device labels is inaccurate. In fact, as detailed below, to the extent Siemens conducted stability testing on the temperature conditions under which its products are actually shipped, such testing has demonstrated that certain devices either fail or are not safe and effective within the shelf life stated on the device labels.

96. As earlier noted, Siemens IVDs, including products that are contract-manufactured for Siemens by other companies, are stored at, and shipped within the United States from the ADC in Plainfield, Indiana. The Siemens products shipped from the ADC are temperature sensitive. These products require some form of temperature control to remain stable and capable of performing as intended. Upon information and belief, hundreds of Siemens IVD devices must be refrigerated at a specified temperature range of 2-8° C; other IVD devices have higher or lower ranges; and some IVD devices must be kept frozen.

97. These devices were cleared or approved by FDA for specific temperature ranges. FDA cleared or approved each device based, in relevant part, on stability data purporting to establish that the device was safe and effective within a specified temperature range to work as intended and remain shelf stable for a specific period.

98. Siemens ships more than 100,000 temperature-sensitive products from the ADC each month. It ships these devices to other distribution centers, to other distributors, and to

end-users like hospitals, laboratories and other customers. Upon information and belief, when a customer places an order from Siemens, the product is pulled from the ADC warehouse, placed in the shipper, labeled, packaged, and given to a carrier (such as FedEx, UPS, etc.) for distribution. In the process, the devices are ***not*** kept within temperature-controlled storage conditions. Rather, products are removed from temperature-controlled storage conditions up to hours at a time in order to be packaged for shipment.

99. Siemens uses a container called a "shipper" to ship devices from the ADC. A shipper is a corrugated box with a foam lining used to ship temperature-sensitive items. When done correctly, various kinds of refrigerants (*e.g.*, dry ice or gel packs) may be added to a shipper in order to preserve the temperature of the cargo carried within at required ranges. However, Siemens' shippers and procedures for preparing shippers for distribution are woefully inadequate. Upon information and belief, Siemens uses the same few shipper designs and procedures for all products regardless of temperature requirements. As detailed below, those procedures are insufficient to ensure that devices are maintained within required temperature ranges.

100. Siemens' own internal documents, and the statements of Siemens personnel, including recorded conversations, prove that these actions resulted in the knowing delivery to customers all across the health care industry of countless adulterated and misbranded IVDs that were relied upon in diagnosing medical conditions in order to cure, treat, mitigate or prevent disease. These actions, as Siemens' own written and oral admissions establish, created serious patient and public safety risks arising from the delivery of unreliable IVDs that could not be trusted to operate in a manner consistent with their design and performance specifications, as required to provide accurate measurements for diagnosis and treatment of a wide range of medical conditions. Even more disturbing, the facts reveal that Siemens took these dangerous and irresponsible actions

for the basest of reasons – *i.e.*, in order to save money on its product distribution costs, thereby knowingly elevating profit over safety.

a. Siemens' Knowledge Concerning the Inability of Its "Shippers" To Maintain the Required Temperature Ranges of Refrigerated and Frozen IVDs During the Product Distribution Process

101. Siemens has long known that its shippers are egregiously deficient based on field tests and other information showing that shipped IVD devices reach temperatures well outside their approved or cleared temperature ranges. This knowledge extends to individuals at some of the highest levels within Siemens, including various Siemens' Vice Presidents and the Siemens Medical CEO. Yet, Siemens has continued to ship its devices in these non-compliant conditions, knowing that doing so renders the IVDs adulterated and misbranded, severely compromises their reliability and efficacy, and jeopardizes patient health. '

102. Between at least 2009 and 2015, Siemens hired companies to perform testing that showed the shippers it was using failed to maintain devices within required temperature ranges. In 2009, Siemens engaged ISC Tegrant Labs ("ISC Labs"), which is owned by Thermosafe (the company that manufactures the shippers used by Siemens) to test the shippers that Siemens was using to deliver its IVDs from the ADC. *See* ISC Labs, Ambient Profile Development Report (Apr. 9, 2009), attached hereto as Exhibit 11. Siemens utilized ISC Labs to conduct similar testing in 2010, 2012, and 2014. *See, e.g.*, ISC Labs Test Worksheet, Winter Profiles (July 2010), attached hereto as Exhibit 12; ISC Labs, Summer Ambient Profile (Dec. 2012), attached hereto as Exhibit 13; ISC Labs, Summer Gels (Apr. 2014), attached hereto as Exhibit 14.

103. In 2015, Siemens hired a firm called BioConvergence ("BioC") to conduct similar tests on the same shippers. *See* BioConvergence Project 1 Position Paper (Nov. 25, 2015), attached hereto as Exhibit 15; BioConvergence Shipper Field Testing Summary Report (Nov. 25, 2015), attached hereto as Exhibit 16; BioConvergence Shipper Thermal Simulation Testing Summary

Report (Nov. 25, 2015), attached hereto as Exhibit 17. Both sets of tests examined whether Siemens could effectively deliver its temperature-sensitive IVDs using its shippers, without subjecting IVDs to temperatures outside their FDA-approved or cleared ranges.

104. Both sets of testing (*i.e.* by ISC Labs and BioC) revealed across-the-board failures of Siemens' shippers.

i. Siemens' Testing at ISC Labs

105. In 2009, Siemens engaged ISC Labs to test the Siemens' shippers to determine if they were qualified to keep refrigerated (2°-8°C) devices within a 2-8°C range during shipping. That same year, in its first report, ISC Labs alerted Siemens's Transportation and Logistics groups that, depending on the season, a shipper experienced temperature ranges from 38°C to -8°C in the course of 56 hours, where the typical shipping cycle of the IVDs contained within the shippers was 48 to 72 hours. These temperatures extended well beyond the required range of 2-8°C. *See* ISC Labs, Ambient Profile Development Report, Exhibit 11. This report also evaluated the type of packaging available for use in shippers, recommending the "develop[ment] of a thermal packaging system for shipping temperature-sensitive products." *Id.* at 9.

106. Siemens conducted similar testing in 2010, 2012, and 2014 with ISC Labs. The shippers again failed each of these tests. For example, the 2010 test showed that Siemens products that were supposed to maintain a temperature of 2-8ºC actually experienced, within 25 hours, temperatures below 0°C, and, within 36 hours, temperatures above 20°C. *See* Exhibit 12 (showing temperatures of -0.1°C at 23.75 hours); Exhibit 13 (showing temperatures of 22.6° at 36 hours).

ii. Siemens's Testing at BioConvergence

107. In late 2013, Siemens Healthcare Diagnostics, Inc. approached BioC to assist with thermal management of products in the distribution process. The stated goal of the project was "[d]etermin[ing] and document[ing] the performance of a representative sample of current

packaging methods and practices utilized by Siemens for shipments in the Intra US/Canada and Ex US shipping lanes during periods of normal seasonal 'High and Low' temperature ranges for the chosen shipping lanes including the 'last mile' to customers for the US and Canada Lanes." BioConvergence Project Presentation PowerPoint, attached hereto as Exhibit 15 (at 28) and 18 (at 3) . Relator has extensive knowledge of this testing because she worked on this project at BioC.

108. Siemens formally engaged BioC for this work in August 2014. *See* Aug. 28, 2014 Cover Letter to Contract (BioC Contract), attached hereto as Exhibit 19. The contract set out a "Shipper Qualification" project, with the goal of "gather[ing] information about a subset of current shippers, processes and capabilities." Siemens summarized the project as focusing on "evaluating and documenting performance of several current thermal packaging configurations (Shippers) intended to keep products at 2-8°C even when exposed to extreme temperatures of shipping lanes (Routes) routinely used by Siemens." *Id.* The project also examined shippers intended to keep products frozen.

109. Siemens approved the protocols governing BioC's tests for "qualifying" the shippers (*i.e*, assessing whether the shippers-maintained devices within the required temperatures ranges). The "objective" of the project, as set out in the protocols, was "to qualify the[] shippers" to assure that they would "maintain temperature specifications." BioConvergence, Phase 1: 2°-8°C Shipper Qualification Protocol (Oct. 3, 2014), attached hereto as Exhibit 19, at 5. Specifically, the protocols stated that the project's aim was to test "the capability of the shippers to maintain the desired 2-8°C, or frozen/dry ice temperature range for the package contents." *Id.* at 6, 11 ("The thermal profile of the interior thermal recording device(s) within the various shippers will portray the capability of the shipper to maintain the 2-8°C, or frozen/dry ice environment throughout the duration of the test.").

110. Siemens designed the tests to reflect actual shipping conditions, including realistic

shipping durations. Siemens's contract stated that BioC would test "the performance of a representative sample of current packaging methods and practices utilized by Siemens for shipments in Intra US." and that the tests would be based on the very "shipping lanes (Routes) routinely used by Siemens." *See* BioC Contract, Exhibit 18. The tests included both lab tests and field tests. The field tests, as set out in the Siemens-approved protocols, were run using Siemens's actual operational methods. *See* BioConvergence Shipper Qualification Protocol Exhibit 19, at 7 ("Each shipper will be packed with a specified typical load . . . using the client's standard operating procedures and with an appropriate pack-out configuration for the time of year according to the client's ordering processing procedure." "Pick, pack, and shipping operations for the field test will be conducted using a Tuesday or Wednesday operational method at ADC."). Following Siemens' own procedures, some packages were sent by FedEx air, while others were sent by FedEx two-day or FedEx ground for delivery. *See id.* at 10; *see also* BioConvergence Shipper Field Testing Summary Report (Nov. 25, 2015), Exhibit 16, at 5-6. BioC used the "carrier service level" (*i.e.*, overnight, two-day, or ground) that matched Siemens's standard operating procedures. *See* BioConvergence Shipper Field Testing Interim Summary Report (June 2, 2015), attached hereto as Exhibit 20, at 4 ("Carrier service level was also determined based on destination and Siemens site specific procedure."); *see also* Exhibit 16, at 4

111. BioC monitored shipper internal temperatures only during shipment, but Siemens did not have BioC assess the temperatures to which devices were exposed during other phases of the overall shipping process. Specifically, "[t]he [monitors] were used to capture the actual temperature that products were exposed to *during shipment*." BioConvergence Shipper Field Testing Summary Report, Exhibit 16, at 3 (emphasis added)). Significantly, in addition to shipping, IVDs are exposed to environmental stress temperatures in at least three other phases: (i) the packaging process; (ii) the loading process, including sitting on a FedEx truck awaiting departure;

and (iii) the receiving process, in which products often may not be placed in a refrigerator or freezer immediately upon receipt. These processes may add another 14 or more hours to the amount of time an IVD is exposed to environmental stress temperatures.

112. These additional, unmeasured periods of exposure to environmental temperature stress were obvious to Siemens. In April 2015, for instance, Siemens opened a corrective and preventative action ("CAPA"), CAPA 4889, to address the first additional period of exposure, *i.e.*, during the packaging process. *See* Siemens Corrective Action and Preventive Action #4889 attached hereto as Exhibit 21, at 1. That CAPA documented that the ADC had "no objective evidence that products requiring 2-8ºC storage are not exposed to temperatures outside that storage range during processing, for less than two hours, as required" by Siemens protocols. *Id.* Similarly, the testing by BioC highlighted that a recipient of a shipment is unlikely to immediately open the package and store it appropriately. In particular, the testing reported that BioC learned through its field tests that shippers were "not immediately opened upon delivery" but, instead, "may be held for some period of time prior to unpacking." BioConvergence Shipper Field Testing Summary Report, Exhibit 16, at 6; *see id.* at 9. Thus, the environmental temperature stresses on devices during shipment are only a part of the overall temperature stress endured by the IVDs. The overall length of temperature stress necessarily exceeds the period of time reported by the BioC testing, probably by double-digit hours.

113. As for the shipping interval that BioC measured, the BioC tests showed that the Siemens shippers failed across-the-board. BioC's ultimate work product for Siemens was a slide deck dated November 25, 2015, which Relator partially authored. *See* BioConvergence Project Presentation PowerPoint, Exhibit 15. That presentation concluded that Siemens's "Shippers failed to maintain internal temperatures within specified ranges," and that, accordingly, "[t]he Shippers are not qualified." *Id.* at 32. This conclusion was true for both refrigerated shippers and dry ice

shippers. *See id.* at 16. As the report detailed, "2-8°C Shippers are unable to maintain 2-8°C temperature specification range" and "Dry Ice Shippers are unable to maintain ≤ 20°C temperature specification." *Id.* Both categories of shippers (refrigerated and dry ice) failed both types of tests: field testing and lab simulation testing. *See id.* at 14-15; *see also* BioConvergence Shipper Field Testing (Interim) Summary Report, Exhibit 20, at 10; BioConvergence Shipper Thermal Simulation Testing (Interim) Summary Report (June 2, 2015), attached hereto as Exhibit 22, at 9.

114. Because the dry ice shippers failed even *winter* field testing conditions, Siemens instructed BioC to cancel the summer field testing because the results during the summer heat would have been even more egregious than the failures in the cold of winter. *See* BioConvergence Shipper Field Testing Summary Report, Exhibit 16, at 13. Moreover, and significantly, the field tests failed at all levels of FedEx service—*i.e.*, ranging from FexEx Ground to FedEx Air. *See id*.

115. Even worse, Siemens's shippers failed BioC's testing *quickly*. For instance, shippers came in all sizes (*e.g.*, extra-small, small, medium, and large). The refrigerated devices in the extra-small shipper were subjected to temperatures above the 8°C limit within "the first 20-24 hours of [the] hot profile thermal simulation." BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), attached hereto as Exhibit 23, at 26. The extra-small shippers likewise "experienced excursions below 1.5°C beginning early in the winter field test trips." *Id.* BioC concluded that this particular shipper was "vulnerable to low temperature excursions" and "very vulnerable to high temperature excursions." *Id. See, e.g.,* BioConvergence, Attachment D - Temperatures and Modes, attached hereto as Exhibit 24 (BioC Field Test, Attach. D, Temps and Modes), at 1, 12 (NY extra-small shipper failing winter conditions within 10 hours; Texas and Florida extra-small shippers failing summer conditions within 24 hours).

116. The small shipper similarly failed field testing quickly, with "internal low temperature excursions below 1.5°C beginning early in the field test trips regardless of ship method

or destination," and reaching temperatures above the refrigerated limit in hot profile testing "[a]fter the first 17 to 22 hours." BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23, at 35-36; *See, e.g.,* BioConvergence, Attachment D - Temperatures and Modes, Exhibit 24, at 21 (showing Minnesota small shipper failing winter conditions within 12 hours); *see also id.* at 32 (showing Texas small shipper failing summer conditions within 24 hours).

117. Tests of the medium and large shippers revealed the same quick failures. *See, e.g.*, BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23, at 53-54 (showing medium shipper failed winter field tests "beginning early in the field test trips" and summer field and simulation tests, as well); BioConvergence, Attachment D - Temperatures and Modes, Exhibit 24 at 39, 42 (Minnesota medium shipper failing winter conditions within 12 hours; California medium shipper failing winter conditions within 24 hours); BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23 at 69 ("large box is vulnerable to internal low temperature excursions" "the field results . . . show the large box experiencing internal low temperature excursions below 1.5°C beginning early in the field test trips").

118. As for the dry ice shippers, which Siemens used to ship its deep freeze category of devices, those failed at the very beginning of the tests with temperature "high excursions" "last[ing] from a few minutes to 1.5 hours." BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23, at 97. In light of that immediate failure, even in the cold of winter, Siemens abandoned any summer field testing for the dry ice shippers.

119. The documented failures included: (i) frozen shippers experiencing thawing conditions; (ii) refrigerated shippers experiencing freezing conditions; and (iii) refrigerated shippers experiencing hot conditions, as follows:

- **Frozen devices were subjected to thawing conditions.** Although Siemens called off the critical testing (*i.e.*, the summer field tests) because the

shippers failed even in winter conditions, the summer thermal simulation testing (generally milder than summer field tests) showed thawing conditions (*i.e.*, > 0°C) within 37-48 hours, and that, by 72 hours, the inside of the shipper was, on average, as high as 28.7°C. *See* BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23 at 91, 95.

- **Refrigerated devices were subjected to freezing conditions.** With respect to refrigerated shippers, BioC testing showed that products would be exposed to near-freezing temperatures within 24 hours (*see, e.g.*, citations in prior paragraph), and would be exposed to freezing and below-freezing temperatures within 36 hours. *See* BioConvergence, Attachment D - Temperatures and Modes, Exhibit 24 at 1. Siemens's prior ISC Labs testing—which Relator later obtained—likewise showed that refrigerated shippers exposed devices to freezing conditions within 24 hours. *See* ISC Labs Test Worksheet, Winter Profiles (July 2010), Exhibit 12 at 1-2.
- **Refrigerated devices were subjected to overly warm or hot conditions.** Refrigerated devices also exceeded the 8°C limit within 24 hours, *see, e.g.* BioConvergence, Attachment D - Temperatures and Modes, Exhibit 24 at 32, with temperatures above 30°C, *see, e.g.*, BioConvergence Project Presentation PowerPoint, Exhibit 15, at 14.

120. BioC presented these across-the-board failures to Siemens in its final slide deck presentation and called out regulatory requirements, such as the QSR, impacted by those failures. *See* BioConvergence Project Presentation PowerPoint, Exhibit 15, at 19-22. BioC recommended, as the very first step, that Siemens "immediate[ly]" implement a CAPA to "address [Siemens's] current compliance risk in deviating from [its] current temperature specification requirements." *Id.*

at 28 (Action item #1). In addition, BioC recommended that Siemens "immediate[ly]" "[w]ork with [its] existing supplier to improve current shipper to meet specification[s]" or to "[s]ource possible shippers from other suppliers." *Id.* BioC recommended that Siemens complete these immediate actions within less than six months. *See id.* at 27-28. On information and belief, Siemens has taken no meaningful action to do so, and the deficient shippers remain in use today.

121. Thus, based on the Siemens-commissioned, independent analyses of both ISC Labs and BioC, Siemens was aware since at least 2009 that the shippers used by the company to transport IVDs to customers resulted in exposure of IVDs to temperatures well outside of their FDA-approved frozen or refrigerated ranges, rendering the shipped devices both adulterated and misbranded, with no assurances of reliability, safety or efficacy.

b. The Representative Cardiac Troponin IVD And Siemens' Admissions Concerning the Public Health Risks of Using "Shippers" That Do Not Maintain IVDs Within Required Temperature Ranges

i. Admissions Concerning the Malfunctioning of The Cardiac Troponin IVD When Exposed to Non-Compliant Temperature Conditions Outside FDA-Approved Ranges

122. The severity of Siemens' misconduct concerning the shipping and distribution of adulterated and misbranded IVD products, and Siemens' private acknowledgment of the public health risks that these compromised IVDs created, is well-encapsulated by Siemens' actions and admissions relating to its menu of Cardiac Troponin IVDs. On information and belief, the public health risks arising from Siemens' misconduct relating to the shipping and distribution of the Cardiac Troponin IVD are merely representative of similar risks for other Siemens IVDs that were likewise rendered adulterated and misbranded by the same knowing and reckless behavior.

123. The Cardiac Troponin IVD diagnoses acute myocardial infarction, commonly known as a heart attack. It works by measuring troponin levels in patients who show signs and symptoms of a possible heart attack. Troponin is a protein found in heart muscle and released into

the blood stream when there is damage to the heart. *See* Am. Assoc'n for Clinical Chemistry, "Troponin," *available at* https://labtestsonline.org/understanding/analytes/troponin/tab/test/. Troponin tests are typically ordered when a person with a suspected heart attack comes into an emergency room. *See id.* The Cardiac Troponin IVD tests specimens to determine whether a patient is, in fact, suffering from a heart attack.

124. One component of the Cardiac Troponin IVD is the reagent. An analyte specific reagent ("ASR") is defined as "antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reactions with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens." 21 CFR 864.4020(a). For the Cardiac Troponin IVD, the ASR is intended to identify raised cardiac troponin levels in the body as the key biochemical marker for a heart attack. The ASR for the Cardiac Troponin IVD must be maintained in a refrigerated state at 2-8^{o} C in accordance with FDA requirements. As noted in paragraphs 102-122 above, however, Siemens' shippers are unable to maintain IVDs in a refrigerated condition, hence rendering the Cardiac Troponin IVD adulterated and misbranded at the time of delivery.

125. Another component of the Cardiac Troponin Assay is the control. A control material is an "external sample . . . run in parallel with patient samples to assess the analytical reliability of the total analytical test system." FDA, Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices (Feb. 1, 1996), at 3. The Cardiac Troponin controls were previously given Siemens material numbers KC681, KC682, and KC863; Siemens changed the material numbers to 1070956, 1070957, and 1070958. *See* Excerpts of DQSP-00033-A4, Exhibit 7.

126. The Cardiac Troponin controls are temperature sensitive, which is typical of IVD components. *See* Siemens Sept. 11, 2015 Mem., Exhibit 5. As Siemens's corporate documents acknowledge, "most of the In Vitro Diagnostic Products contain[] proteins or enzymes which are very temperature sensitive." *Id.* at 1. Siemens defines four standard and shipping conditions: (i) deep frozen (-60°--80°C); (ii) frozen (-15°- - 25°C); (iii) refrigerated (2°-8°C); and (iv) controlled ambient (15°-25°C). *See* Siemens Global Procedure GP-033, Product Protection for Reagents and Disposables (May 16, 2012), Exhibit 6, at 4. Siemens's policies state that these required temperature conditions must be established based on stability data during product development. *See id.* at 5; *see also* Siemens Sept. 11, 2015 Mem., Exhibit 5, at 1. The Cardiac Troponin controls must be stored in frozen conditions, *i.e.*, between -15°C and -25°C. *See* Excerpts of DQSP-00033-A4, Exhibit 7.

127. Siemens' documents reflect that, during shipping, the Cardiac Troponin controls "must remain frozen at all times." Siemens Global Procedure GP-033, Product Protection for Reagents and Disposables (May 16, 2012), Exhibit 6 at 11. Siemens uses a system of rise and fall codes to define acceptable and unacceptable temperature excursions for devices. If a device exceeds the upper temperature ceiling set in a "rise" code, it must be quarantined; and if a device exceeds the lower temperature floor set in a "fall" code, it likewise must be quarantined. *See id.*, at 8-9. Siemens maintains a spreadsheet called "GP-033 Attachment 4," or the "A4," which details "the standard storage conditions, the shipping conditions," and all temperature rise and fall codes. *Id.* at 8. Siemens's policies state that the company assigns rise and fall codes "only to product which have supporting data." *Id.* For the Cardiac Troponin controls, GP-033 Attachment 4 assigns rise code 7. *See* Excerpts of DQSP-00033-A4, Exhibit 7. That code means that the Cardiac Troponin controls "*must remain frozen at all times*" and that "[n]o freeze/thaw cycles can be

tolerated." Siemens Global Procedure GP-033, Product Protection for Reagents and Disposables (May 16, 2012), Exhibit 6, at 11.

128. The reason Siemens assigned rise code 7, which does not permit the Cardiac Troponin controls to be exposed to thawing conditions during shipping, is due to stress testing that Siemens conducted on the controls. *See* Interim Stability Report, LOCI Cardiac Troponin-I Control (KC681, KC682, KC683) (July 2, 2012), attached hereto as Exhibit 25. That test briefly exposed the controls of one of Siemens' Cardiac Troponin assays – the LOCI Cardiac Troponin-I – to thawing conditions. *See id.* After that exposure, the controls were placed in storage at appropriate conditions and tested for functionality. While Siemens claimed a stated shelf life of eight (8) months, the experiment showed that "[t]he test material stored at these conditions failed to meet allowable guideline[s] after 1 month." *Id.* at 4. Indeed, the stress test demonstrated that the product failed at the very first test point (*i.e.*, before month one, on day 17 of study). *See id.* at 12; *see also* Email Exchange, dated Feb. 16, 2016, attached hereto as Exhibit 26 (email from Siemens biochemist, explaining "[t]he troponin antigen . . . is known to decay over time in refrigerated temperatures").

129. In other words, the "product [was negatively] affected by . . . Freeze/Thaw." *Id.* Siemens thus concluded that Cardiac Troponin controls cannot function properly if they are exposed to thawing conditions (*i.e.*, conditions above 0°C). *See id.* Siemens determined that the potential public health risks arising from shipping these devices outside their rise codes could be highly significant. For every device, Siemens analyzes the risks presented by different problems that may arise in the manufacturing, shipping, or use of its devices. Siemens records its conclusions in spreadsheets known as Failure Mode and Effects Analyses (FMEAs). For its troponin assays, Siemens specifically considered the risk, during "ship[ping] to customers," presented if "[k]its [are] dispatched to customers at incorrect temperature[s] leading to degradation of [the] finished

kit." Excerpts of Troponin FMEA Spreadsheet, Exhibit 9, at row 307. That scenario could lead to either an "[e]levated [e]rroneous result" or a "[d]epressed [e]rroneous result." *Id.* The former, according to Siemens, would lead to harm in the form of "[u]nwarranted cardiac catherization," and the latter would lead to harm in the form of "[m]isdiagnosis or delayed intervention of myocardial infarction." *Id.* Siemens has determined that these harms would likely flow from shipping outside appropriate temperature ranges, *see id.*, and that such harms are respectively "Moderate" (*i.e.*, resulting in "injury or impairment typically requiring professional medical intervention") and "Major" (*i.e.*, resulting in "death, life-threatening or permanent impairment or injury").

130. Relator also reviewed Siemens records for another Troponin IVD marketed by the company – the Immulite 2000 Troponin I Assay (L2KTI). Line 162 of the FMEA for the L2KTI Troponin IVD sets out Siemens's internal conclusion that shipping the device where "specified shipping temperatures are not maintained" was a high risk ("HR") because such a situation would "likely" lead to an erroneous result of misdiagnosing a heart attack. *See* FMEA L2KTI for Immulite System, attached hereto as Exhibit 27.

131. Siemens' own assessment is thus that shipping Cardiac Troponin IVDs outside their required temperature ranges could be fatal and is, in any event, extremely serious.

132. Yet, as described in detail in paragraphs 102-122 above, Siemens has been knowingly shipping its devices in conditions in which the devices are proven to become unreliable. Specifically, Siemens has been shipping devices in the United States through methods that its own repeated tests have shown expose devices that must be frozen, like the Cardiac Troponin controls, to thawing conditions. As previously noted, the most recent testing of Siemens's device packaging (*i.e.*, "shippers") showed that, using Siemens's typical shipping lanes, the packaging would not

keep devices frozen within 37-48 hours of shipping, *even in the winter*. *See* BioConvergence, Shipper Evaluation Summary Report (Nov. 25, 2015), Exhibit 23, at 91, 95.

133. Senior Siemens officials admitted to Relator that they were concerned about the safety, in particular, of the Cardiac Troponin IVDs. At a meeting held at the ADC on April 4, 2016, attended by Relator, Jörg Amborn (Siemens Vice President for Quality & Technology), Chris Goss (Senior Director Global Transportation), Nancy Taylor (Director, Quality Management and Global Logistics) and Ken Smith (Vice President of Logistics and Supply Chain), Amborn admitted, in words or substance, that "the only product I would be concerned about," from a patient safety standpoint, "would be Troponin." In a subsequent recorded conversation with Nancy Taylor on April 19, 2016, Taylor told Relator "the most critical assays are the ones Joerg told you about, which are the cardiac ones that are immediate, right . . . I think you're right. So those are our highest risk."

134. Yet, even with respect to the Cardiac Troponin heart attack assays that Siemens senior management acknowledged was a critical patient safety concern, neither Amborn nor any others in the group directed immediate corrective action. When Relator suggested that Siemens change to qualified shippers capable of maintaining the IVDs within required temperature ranges – *i.e.,* shippers that were available on the open market and that could solve the problem of non-compliant temperature excursions – Amborn's only response was that he would address the issues at the next Product Lifecycle Management Group meeting at the end of May, and he asked Chris Goss and Nancy Taylor to prepare a short slide deck for him to use at that meeting. On information and belief, however, nothing actually was ever done to address the problem, and Siemens continues to ship Cardiac Troponin IVDs in non-compliant temperature conditions that corrupt the assays' reliability and jeopardize patient health and safety.

ii. Admissions Concerning the Public Health Risks Associated with Using Unqualified Shippers to Transport Siemens IVDs

135. Apart from the Cardiac Troponin assays, Siemens is fully cognizant of the safety risks that non-compliant temperature conditions create for its IVD products generally. Relator personally reviewed FMEA tabs in Siemens risk management files and observed serious risks documented by Siemens as arising from the failure to maintain devices at the correct temperature. *See* FMEA Spreadsheet Excerpts, Exhibits 10A though 10F. Relator also was directly involved in conversations with senior Siemens management personnel, who privately acknowledged the risks created by Siemens' continued use of thermally unqualified shipping containers to transport IVD devices to customers.

136. When the initial BioC field test results in or about March 2015 showed that Siemens was actively using unqualified shippers, Relator contacted her colleagues at BioC, including Kelly Boatman (Siemens's client contact at BioC). Together, Relator and Ms. Boatman contacted Nancy Taylor and Chris Goss at Siemens, and conveyed BioC's results. Siemens's response, as conveyed by Taylor, was that they were "not surprised." Instead of addressing or otherwise escalating the issue, Goss instructed Relator and Boatman not to communicate the information to anyone else. Over the next several months, BioC concluded its testing and analysis showing across-the-board failures of the Siemens shippers. *See, supra*, ¶¶ 108-122.

137. Siemens, however, pressured BioC to provide a report with a positive spin. Chris Goss of Siemens insisted on re-writing the report "as he wanted." Email Exchange of Mar. 18, 2015, attached hereto as Exhibit 28. Relator refused to participate in the project if it ignored the blatant regulatory and safety issues revealed by the testing. *See id.* She informed Siemens that if "the focus will not be on regulatory, I am not going to be involved in drafting [or] reviewing the

document." *Id.* In a follow-up email, Relator expressed her concern that Siemens was focused only "on the short term right now" and was putting the key "regulatory issues (i.e., stability monitoring, etc.)" on the back burner. *Id.* This pressure continued.

138. On April 1, 2015, Goss "expressed disappointment" with the preliminary deliverables, complaining that they "rais[ed] too many questions rather than deliver[ed] answers." Email Exchange of Apr. 1, 2015, attached hereto as Exhibit 29. Goss encouraged BioC to spin the results so that, instead of reporting that the shippers were not qualified—as they plainly were not—BioC might, instead, "tell [a] story of what [the] shippers actually do." Id.; *see* BioConvergence Notes from May 17- 18, 2015, attached hereto as Exhibit 30 ("Chris recommended that we lead with what we know about the shippers (which box is qualified to what temp range for how long"). However, the only scientifically significant result from the BioC testing, as with the ISC Labs testing that was performed previously, was the total incapacity of the Siemens shippers to maintain the FDA-required temperature ranges of Siemens products.

139. As Chris Goss later explained in a recorded conversation, he was "very careful with the verbiage" in ensuring that BioC reported that "Shippers were unable to maintain 2-8 temperature specification ranges," with "no term of failure." Despite this pressure, however, the final BioC slide deck reported that the shippers were not qualified and that Siemens needed to take "immediate action" to improve its shippers or re-source them. BioConvergence Project Presentation PowerPoint, Exhibit 15, at 28. Siemens nonetheless ignored the recommendation in the BioC presentation and, upon information and belief, continues to use the same thermally unqualified shippers today.

140. While working at Siemens, Ms. Wood had access to additional documents revealing the extent of the dangers caused by Siemens' refusal to reform its shipping practices. Siemens provided her with an Excel spreadsheet, the DQSP00033-A4, which listed Siemens' 4,200

products, the required temperature conditions, and rise and fall codes. *See* Attachment 4, DQSP-00033, Exhibit 4. Relator was concerned that these rise and fall determinations were being made without clearance from, or approval by, FDA. Relator also worried about the existence or quality of any stress testing that might back up their conclusions. Most of all, however, Relator was concerned because she knew—as Siemens also knew from the ISC Labs and BioC testing—that the devices listed in the Excel spreadsheet were being exposed to temperature excursions even more extreme than those purportedly permitted by their rise and fall codes in the normal course of shipping due to Siemens' use of thermally unqualified shippers.

141. Relator also became concerned upon reviewing Siemens' own conclusions, contained in the FMEAs within Siemens' risk management files, that temperature stresses present serious—indeed, sometimes deadly—risks to public health, and can result in the failure to correctly diagnose and treat patients. Relator shared her concerns with Chris Goss, to whom she reported, as well as Nancy Taylor. Relator repeatedly told them that they needed to escalate the issue. For instance, on March 3, 2016, Relator sent an email to Goss and Taylor reiterating her concerns and emphasizing her belief that there were "significant regulatory/compliance risk[s] with [Siemens's] temperature specifications for shipping/ distribution conditions." *See* Email of Mar. 3, 2016, attached hereto as Exhibit 31. Relator recommended that the team "rais[e] the issues to higher levels of Management" to make the issue a "priority." Id. In the evening of Friday, March 4, 2016, Nancy Taylor responded by commending Relator for her "ethical soul!" Email of Mar. 4, 2016, attached hereto as Exhibit 32. However, the next business day, Monday, March 7, 2016, Chris Goss of Siemens tried to stop Relator from continuing to discuss this concern. He called Relator just after 8:00 in the morning and, after she called him back, Goss instructed her not to email or put into writing any concerns relating to compliance risk. Goss also expressed concern about Nancy

Taylor's frank reply to Relator and shared that he had likewise instructed Taylor not to discuss these compliance issues in writing.

142. Relator did not accede to Goss' instruction. Instead, the next day, Relator pressed the issue again with Nancy Taylor, sending an email on March 8 suggesting that Ms. Taylor "send an email or call the Sr. most person you indicated in your email (you mentioned several) of the issues as soon as possible." Email of Mar. 8, 2016, attached hereto as Exhibit 33. Relator reiterated: "timing is critical." Id. Taylor, however, did not address the issue.

143. On March 9, 2016, Relator escalated the issue to Mark Petrille, the U.S. Siemens Healthcare Chief Compliance Officer and Dr. Knothe Benedikt, the Global Head of Siemens Healthcare Compliance. See Email of Mar. 9, 2016, attached hereto as Exhibit 34. Relator reported "potential serious risk to patient[s]" and explained, as the primary concern, that Siemens' shippers "are unable to maintain the temperature requirements." *Id.* Relator stated that she was raising this issue "in the spirit of quality and keeping your customers safe." *Id.* "These issues," she stressed, "must be addressed immediately" and "[a]ny further delay is not acceptable." *Id.* (emphases in original). She insisted that the "issues . . . be escalated to the very Sr. levels of the organization." Id. The email went on to give details about the problem, express frustration that her prior attempts at escalation had fallen on deaf ears and offer to discuss the problem at any time. *Id.* Siemens, however, never took remedial action to correct its shipper problems.

144. On March 14, 2016, Relator had a conversation with Nancy Taylor in which Relator again expressed her concern about Siemens' failure to correct the ongoing problem with thermally unqualified shippers. Taylor admitted to Relator that Siemens had done nothing more than look at whether it had received customer complaints that shipping conditions had caused product failures. Taylor's admission deeply concerned Relator, since a physician looking at a false test result forwarded by a laboratory could not be expected to realize the error, much less that the error

resulted from temperature excursions during shipping of the IVD utilized in performing the test. Likewise, given that the Siemens calibrators and controls needed to ensure proper functioning of IVDs in clinical use were being compromised by temperature excursions during the shipping process, there also was no reason to believe that the laboratories which relied on such calibrators and controls would know that they had forwarded an erroneous test result. In such circumstances, there simply was no legitimate basis for Siemens to assume that customer complaints would even exist, much less that they could ever be a valid proxy for quality control or FDA compliance. Indeed, Taylor admitted that documenting that there were few such complaints simply was the easiest way for Siemens to justify "continuing to ship."

145. After the April 4, 2016 meeting with Amborn, Taylor, Goss and Smith, at which Amborn acknowledged his concern with "Troponin" from a "patient safety standpoint," and requested that Taylor and Goss prepare a short slide presentation for him to use at the next Product Lifecycle Management Group meeting at the end of May (*see, supra,* ¶ 135), Relator asked Chris Goss if she could prepare that slide deck for Amborn. Goss told Relator she could "take a stab," but when Relator drafted and circulated slides, she received no feedback. When Relator followed up again, Nancy Taylor responded by editing out elements of the deck. Specifically, Taylor narrowed the focus from all 4,000-plus temperature-sensitive IVDs at issue to just 500-600 devices that showed no rise or fall codes (*i.e.*, lacked a noted temperature tolerance), notwithstanding that some of the rise and fall codes for the other IVDs reflected that many products could not tolerate temperatures to which the ISC Labs and BioC shipper testing showed they could very well be exposed as a result of the faulty shippers used by Siemens. In Relator's view, therefore, the problem was much broader than 500-600 devices. On information and belief, the final version of the presentation ultimately used by Amborn acknowledged that Siemens must take "immediate action" on "product at risk." See Final PLM Presentation, attached hereto as Exhibit 35.

146. In a recorded conversation with Nancy Taylor on April 19, 2016, Taylor made additional admissions to Relator concerning the safety issues she had raised concerning the unqualified shippers and her decision to escalate the matter within Siemens. Taylor told Relator that due to the escalation, the matter had "gone all the way up to Michael Heinold [Senior Vice President, Supply Chain Management Laboratory Diagnostics, Managing Director, Siemens Healthcare Diagnostics Products] . . . Legal, everybody. They are aware. . . I don't want you to go away thinking we aren't really actually freaking panicked." As noted earlier, Taylor further acknowledged the special concern with the Cardiac Troponin assays, telling Relator they were the "most critical assays" because their diagnosis and treatment implications were "immediate." When Relator commented that she would be "concerned" if the Siemens Cardiac Troponin assay were being used to diagnosis or treat herself, Taylor acknowledged that those tests were "highest risk" and "could delay treatment." At the same time, however, Taylor expressed concern about being too quick to document problems in CAPA reports that might not be "CAPA worthy" because "now FDA can see it."

147. On April 20, 2016, in a recorded conversation involving Taylor, Relator and Chris Goss, in which Goss had made clear that he did not want to use the term "failure" to characterize the results of the ISC Labs and BioC shipper testing (*see, supra,* ¶ 140), Taylor commented, in connection with documenting Siemens' problems with the shippers:

> I don't like to manage shit like this in a CAPA. I'll tell you why. . . . You don't throw your sins out in front that everybody can see. That's why I don't like the way Siemens does it. . . . There's no reason for me to have red alarms flying. . . . We got it; we know. I'm not putting it in a CAPA. Because CAPAs are just like, that's just like letting the FDA come and open your pants. Seriously, this is why I don't want that to be a CAPA. I want it to be a project . . . .

148. In another recorded conversation the same day between Taylor and Relator, Taylor acknowledged that she and Chris Goss were accountable for the issue of IVD shipments that were

"out of conditions" (*i.e.* temperature non-compliant). After Relator explained that the point of escalating her concerns was just to make sure Siemens was "not hurting people," Taylor agreed and replied, "We're not joking, right? We cannot say for sure we're not; we cannot say for sure we are. But you know what? Let's put [an] end to this."

149. On April 27, 2016, Relator and Nancy Taylor met with a sales representative from a company called Cold Chain Technologies, an outside shipper vendor, to explore potential solutions to the problems Siemens was experiencing with thermally unqualified shippers. The meeting was recorded. At the outset of the meeting, Taylor explains that Siemens is "in the midst of cold chain hell" and later admits that Siemens is "in dire need of other, alternative shipping containers." Later, Taylor states that she "is the quality person responsible for [Siemens IVD] distribution in the world" and that "her boss" is Ken Smith, "the VP of what we call Materials and Logistics," even while conceding in a separate recorded conversation with Relator the same day that, having come from the pharmaceutical industry, Taylor was "not a device person" and did not know the rules regarding medical devices. Taylor explained to the vendor that "all Siemens Healthcare diagnostics products are distributed from here [*i.e.,* ADC] or our European distribution center primarily." Taylor further acknowledged that the Cardiac Troponin assay is "our most sensitive product" and must be frozen in dry ice, but then conceded with a dismissive laugh that, currently, Siemens just inserts a "random" amount of dry ice in the shipper and "hopes" that the assay "is still working when it gets there" within the targeted domestic shipping time.

150. On information and belief, ***nothing*** changed in Siemens' shipping practices as a result of Relator's escalation of her concerns or any of the conversations with senior Seimens personnel described above. Despite the extremely serious public health risks acknowledged by Siemens, and in violation of FDA regulatory restrictions requiring that Siemens IVDs be maintained in temperature-controlled conditions to safeguard their reliability, safety and efficacy,

Siemens knowingly continues to ship IVD products in packaging that exposes them to the very risks of malfunction that these regulatory requirements are designed to prevent, and that Siemens itself rated, in relation to its Cardiac Troponin IVD, as potentially fatal.

c. Siemens' Admissions That It Was Sacrificing Patient Safety for Savings on Product Distribution Costs

151. Initially, Relator was at a loss to understand why Siemens continued to ship IVDs in non-compliant temperature conditions that undermined their reliability, safety and efficacy, instead of simply upgrading its shippers to thermally qualified containers that already existed in the marketplace. Relator soon learned, however, that the reason was cost.

152. On or about April 19, 2016, Nancy Taylor told Relator that Jörg Amborn had instructed Taylor to identify qualified shippers, but that both Chris Goss and Ken Smith believed that doing so would be a waste of time. That conversation led to Taylor and Relator meeting with representatives from a well-known and established shipper company named Pelican. In that meeting, Relator learned that Siemens had spoken with Pelican years prior about switching to a thermally qualified Pelican shipper, but then reversed course over cost concerns. After the meeting, Relator asked if she could send Siemens' specifications to Pelican. Taylor said no, even while acknowledging that Siemens had a big problem on its hands with unqualified shippers. As Taylor had acknowledged in her April 19 conversation with Relator, "I don't want you to go away thinking we aren't really actually freaking panicked."

153. While Siemens had every reason to panic because of the harm its non-compliance threatened, Siemens persisted in declining to upgrade its shippers to protect patients. During the remainder of Relator's time at Siemens, she spoke with shippers, including Pelican and Cold Chain Technologies, about potential qualified solutions for Siemens.

154. During that process, she also spoke and corresponded with Thermosafe, Siemens's current shipper supplier. Relator learned that Siemens, apparently to cut cost, had instructed Thermosafe that its shippers could be designed to allow refrigerated products to reach zero degrees (*i.e.*, freezing temperatures), rather than "adding refrigerated mass as buffer between -20°C refrigerants and the product." *See, e.g.*, Apr. 28, 2016 Initial Email with Sally Eggers, attached hereto as Exhibit 36. Siemens did so, despite its own conclusions that many devices could not tolerate freezing temperatures. *See* Attachment 4, DQSP-00033, Exhibit 4. The Thermosafe engineer handling the Siemens account, Sally Egger, recalled that Tony Moran (Siemens Vice President Americas Logistics) "felt he could justify going down to 0°C based on the product stability data ***and the thought was that the extra leeway would lead to more cost effective designs.***" April 28, 2016 Follow-Up Email with Sally Eggers, attached hereto as Exhibit 37 (emphasis added).

155. Relator also learned that Thermosafe had repeatedly offered better solutions to Siemens, which Siemens had refused. *See* Apr. 28, 2016 Initial and Follow-Up Emails with Sally Eggers, Exhibits 36 and 37; Attachment to Apr. 28, 2016 Initial Email listing Siemens Contingency shipper options, attached hereto as Exhibit 38; Additional Apr. 28, 2016 Email with Sally Eggers with attachments (Email attached hereto as Exhibit 39; Attachment 1, Siemens 0-8C Design Summary 4-3-2013, attached hereto as Exhibit 40; Attachment 2, Siemens Thermal Modeling Summary, attached hereto as Exhibit 41; Attachment 3, Small/Medium Ship EPS-Minimum Load-Winter Ambient Profile, attached hereto as Exhibit 42; Attachment 4, Small/Medium Ship EPS-Minimum Load-Summer Ambient Profile, attached hereto as Exhibit 43; Attachment 5, Small/Medium Shipper Minimum/Maximum Loads-Summer Ambient Profile with Frozen Refrigerants, attached hereto as Exhibit 44; Attachment 6, Minimum/Maximum Load Sumer Packout Design, attached hereto as Exhibit 45).

156. One document in particular highlights the lengths to which Siemens went to sacrifice product safety in the interest of cutting marginal costs. The document, bearing ISC Labs' logo and dated April 3, 2013, is entitled, "Siemens Small and Medium Shipper 0-8°C Design Summary." *See* Attachment 1 to Additional Apr. 28, 2016 Email, Exhibit 40. The document compares the costs of a "Strict 2-8°C" (*i.e.*, refrigerated) solution to the costs of, among other things, Siemens's then-current solution. *See id.* For small and medium shippers, the basic cost difference between the current solution and the qualified 2-8°C solution was $10 to $30 dollars per shipper. *See id.* Tellingly, two rows of the matrix included "Freeze Protect" solutions and reflected that Siemens had no such solution as of that time. *See id.* (showing empty columns for each "Freeze Protect" entry under "Current Solution"). Moreover, the matrix compared a qualified 2-8°C solution with "Tony's ideas," which Relator understands to be proposals by Siemens Vice President Tony Moran. *Id.* In each case, "Tony's ideas" proposed equal or lower-cost solutions than the qualified 2-8°C solution. *See id.*

157. Relator was appalled that Siemens would sacrifice patient safety—and knowingly adulterate and misbrand IVD products—just to save some money on shipping containers. From these experiences and others, Relator understood that Siemens could quickly solve most of its temperature excursion problems by upgrading to better shippers and/or shipper refrigerants, including those that Pelican, Cold Chain Technologies and Thermosafe had been trying to sell them. And yet Siemens refused to do so. Relator also learned that Siemens was much more focused on ensuring appropriate shipping temperatures in international markets than in the domestic market in the United States. For instance, Siemens was especially focused on compliance in China. In a recorded conversation with a representative of Cold Chain Technologies on April 27, 2016, Nancy Taylor explained that the Chinese government was "super demanding" and "not allowing [temperature] excursions," that "China is our biggest problem right now" and that "our

immediate need is to find a 2-8 solution because [of] China." Siemens appeared to have no interest in upgrading its shippers for domestic purposes, however, in order to stop distributing adulterated and misbranded IVD products right here in the United States.

158. In sum, Siemens has refused to spend additional money on shippers capable of ensuring proper temperature maintenance for IVD devices during domestic shipping to locations within the United States. Siemens has long been offered qualified shippers (*i.e.*, shippers capable of ensuring the reliability, safety and efficacy of Siemens's devices by maintaining the devices within the FDA-approved or -cleared temperature ranges) by its current shipping company, and by other vendors, but has rejected them. The sole obstacle to Siemens' use of qualified shippers has been its unwillingness to spend more money, and it thus has knowingly and unconscionably elevated corporate profits over compliance and patient safety.

C. Siemens' Misconduct Caused Massive Losses to The Government by Inducing Federal Health Care Programs to Reimburse Claims Based on The Use of Unreliable and Functionally Compromised IVDs That Were Neither FDA-Compliant Nor Medically Necessary, And By Inducing Government Agencies To Pay For Such Medical Devices In Material Breach Of Contracting Requirements.

157. Siemens' liability under the FCA for causing customers of adulterated, misbranded, medically unnecessary and professionally inappropriate IVDs to submit claims to Government payers is clear. As noted earlier, the FCA reaches not just those who directly present false claims to the Government, but also those who cause innocent third parties to submit such claims. Siemens caused others to submit false claims to Federal Health Care Programs for the use of its compromised IVD products. Those false claims, unwittingly submitted to Federal Health Care Programs by providers across the country, did not disclose what Siemens had purposefully concealed, *i.e.*, the compromised reliability, safety and efficacy of the IVDs resulting from Siemens' non-compliance with FDA medical device laws and regulations. Such non-compliance

rendered us of Siemens IVDs unreasonable, unnecessary and professionally inappropriate, and thus was highly material to the Government's payment decision. Siemens' deceit in purposefully not disclosing its regulatory non-compliance and the true condition of its IVD products rendered those claims materially misleading and actionable under the FCA. *See, supra,* ¶¶ 58-71.

158. Siemens also sold those compromised IVD products directly to the Government in violation of both express and implied contract payment terms. Siemens' misconduct violated express contract language requiring that such IVDs comply with FDA regulations as a material condition of payment. Moreover, each contract implicitly required as a material condition of payment that any IVDs being purchased by the Government would be reliable, safe and effective, and not adulterated or misbranded. Certainly, no direct purchaser of IVDs would knowingly pay for Siemens devices that could not meet such bare minimum requirements and expectations, which were an assumed part of the implied covenant of good faith and fair dealing that imbues every contract. Siemens' failure to disclose its regulatory and contractual non-compliance, and the true condition of its IVD products, subverted the very purpose of its agreements with the Government, and rendered all claims for payment under Government purchasing contracts materially misleading and actionable under the FCA. *See, supra,* ¶¶ 72-76.

159. Due to the widespread nature of the problems with Siemens IVDs created by Siemens' systematic failure to ensure that domestic IVD shipments complied with FDA-mandated refrigerated and frozen temperature ranges, the full extent of non-compliant devices is not currently known, and so an accurate projection of estimated damages is difficult to calculate. However, the high number of tainted IVDs that were knowingly introduced into interstate commerce by Siemens and paid for with Government funds (*see*, *supra*, at ¶¶ 77-84), may reasonably be expected to lead to damages totaling billions of dollars.

160. Some sense of the scope of financial harm caused by Siemens' misconduct can be obtained by considering that, out of approximately $3.6 trillion in total healthcare expenditures in the United States, roughly 21% is paid for by Medicare, with Medicaid paying for about another 16%. *See* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet. If one uses the Cardiac Troponin assay as an example, it is not difficult to arrive at an astronomical estimated loss amount based solely on these two Federal Health Care Programs, without even taking into account other government insurance programs or direct IVD purchases by government agencies.

161. The FMEA for the Cardiac Troponin assay states that during a six-month review of sales, 397,300 products were sold representing approximately 57,951,168 patient tests. *See* Design FMEA for LOCI Product Family, RISK-00086-GLA, attached hereto as Exhibit 46, at row 57. The 2017 CMS Clinical Laboratory Fee Schedule establishes a mid-point reimbursement of $18.24 for an Assay of troponin quant diagnostic procedure. *See* CMS, 2017 CMS Clinical Laboratory Fee Schedule, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files-Items/17CLAB.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

162. As an illustrative matter, one can project damages relating to the 57,951,168 patient tests in a six-month period. 20% of procedures billed to Medicare yields 23,180,467 Medicare reimbursements for patient tests using these devices for every year of sales (totaling 231,804,670 tests over a ten-year period). Using the reimbursement figure of $18.24 per test yields $422,811,721.73 in Medicare reimbursement per year. Over a ten-year period, it is reasonable to infer that Medicare would have reimbursed over $4.2 billion for tests in just this one subcategory. Under the FCA, moreover, this amount would be trebled, and mandatory civil monetary penalties would apply to each of the tens of thousands of false claims that were submitted.

163. Medicaid programs would also incur substantial losses, even using just the same subcategory as an illustration. Medicaid pays for approximately 16% of all personal healthcare expenditures (18,544,374 tests per year, for a total of 185,443,737 tests over ten years). On the same assumptions as above, and using a New York State fee schedule of $8.05 per test, Medicaid programs would have paid approximately $149,282,208.77 per year for tests utilizing this device, with a total of over $1.49 billion over a ten-year period, again, just for this one IVD. Under the FCA, moreover, this amount would be trebled, and mandatory civil monetary penalties would apply to each of the tens of thousands of false claims that were submitted.

164. In addition, Siemens is liable under the FCA for instances in which it sold compromised medical devices directly to Government purchasers such as the VA or DOD. Siemens received many millions of dollars in Government contracts for adulterated and misbranded IVD products that were unreliable and unsafe, and that did not satisfy material contractual terms mandating that the products comply with FDA regulatory requirements. Under the FCA, Siemens would be liable for treble the amounts paid under these contracts for non-compliant IVDs, in addition to a mandatory civil monetary penalty for each false claim for payment made to the Government under those contracts.

* * * *

165. In conclusion, the facts detailed above – ***including numerous admissions made by Siemens through internal business records and oral statements*** – demonstrate that:

(a) Siemens ***knew*** that exposing IVDs required to be refrigerated or frozen to conditions outside those FDA-approved temperature ranges would compromise their reliability, safety and efficacy and create risk of serious patient harm;

(b) Siemens ***knew*** for years that its shippers and shipping protocols were exposing refrigerated and frozen IVDs – including its "most sensitive" and "highest risk" IVDs like the

Cardiac Troponin assay – to conditions far outside FDA-approved temperature ranges (causing frozen IVDs to thaw, refrigerated IVDs to freeze and refrigerated IVDs to become warm or hot), but was content to "hope" that its devices would be "still working" upon delivery;

(c) Siemens ***knowingly*** chose to continue shipping IVD's products in non-compliant temperature conditions rather than change its shipping practices and invest resources in securing thermally qualified shippers despite serious IVD performance issues and public health risks in order to save money on distribution costs;

(d) Siemens' ***undisclosed and unauthorized actions*** in knowingly shipping IVDs in non-compliant temperature conditions rendered those devices adulterated and misbranded under FDA laws and regulations, unreasonable, unnecessary and inappropriate for clinical use, and unqualified for reimbursement or payment by the Government; and

(d) Siemens nonetheless ***knowingly*** submitted and caused the submission of false claims to the Government based on the acquisition and use of its FDA non-compliant, unreliable and unsafe IVDs.

COUNT I
Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(A))
Presentation of False Claims

166. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

167. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Government and/or to contractors, grantees, or other recipients of Government funds used to advance Government interests, false and fraudulent claims for payment in connection with their introduction into interstate commerce of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications.

168. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

169. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT II

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(B))
Use of False Statements

170. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

171. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, made, used, or caused to be made or used, false records and/or statements material to false or fraudulent claims to the Government and/or to contractors, grantees, or other recipients of Government funds used to advance Government interests, in connection with their introduction into interstate commerce of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications.

172. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

173. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT III

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(C))
Conspiracy

174. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

175. Defendants conspired between and among themselves to commit the violations set forth in the preceding claims.

176. The Government paid claims and incurred losses, and/or contractors, grantees, or other recipients of Government funds used to advance Government interests paid claims and incurred losses, as a result of Defendants' wrongful conduct.

177. By reason of such false and/or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

COUNT IV

Violation of the Alaska Medical Assistance False Claim and Reporting Act (Ak. Stat. § 09.58.010 *et seq.*)

178. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

179. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Alaska and/or to contractors, grantees, or other recipients of the State of Alaska funds used to advance the State of Alaska's interests, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Alaska.

180. The State of Alaska paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Alaska funds used to advance the interests of the State of Alaska paid claims and incurred losses, as a result of Defendants' wrongful conduct.

181. By reason of such false and/or fraudulent claims, the State of Alaska has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

182. Pursuant to Ak. Stat. § 09.58.010(c)(1), the State of Alaska is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false

or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT V

Violation of the California False Claims Act (Cal. Govt. Code. § 1265 *et seq.*)

183. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

184. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of California and/or to contractors, grantees, or other recipients of the State of California funds used to advance the State of California's interests, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of California.

185. The State of California paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of California funds used to advance the interests of the State of California paid claims and incurred losses, as a result of Defendants' wrongful conduct.

186. By reason of such false and/or fraudulent claims, the State of California has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

187. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VI

Violation of the
Colorado Medicaid False Claims Act
(Col. Rev. Stat. § 25.5-4-303.5 *et seq.*)

188. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

189. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Colorado and/or to contractors, grantees, or other recipients of the State of Colorado funds used to advance the interests of the State of Colorado, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Colorado.

190. The State of Colorado paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Colorado funds used to advance the interests of the State of Colorado paid claims and incurred losses, as a result of Defendants' wrongful conduct.

191. By reason of such false and/or fraudulent claims, the State of Colorado has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

192. Pursuant to Col. Rev. Stat. § 25.5-4-305, the State of Colorado is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VII

Violations of Connecticut False Claims Act
For Medical Assistance Programs
(Conn. Gen. Stat. § 17b-301 *et seq.*)

193. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

194. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Connecticut and/or to contractors, grantees, or other recipients of the State of Connecticut funds used to advance the interests of the State of Connecticut, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Connecticut.

195. The State of Connecticut paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Connecticut funds used to advance the interests of the State of Connecticut paid claims and incurred losses, as a result of Defendants' wrongful conduct.

196. By reason of such false and/or fraudulent claims, the State of Connecticut has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

197. Pursuant to Conn. Gen. Stat. § 17b-301b, the State of Connecticut is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT VIII

Violation of the
Delaware False Claims and Reporting Act
(Del. Code. Ann. tit. 6, § 1201 *et seq.*)

198. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

199. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Delaware and/or to contractors, grantees, or other recipients of the State of Delaware funds used to advance the interests of the State of Delaware, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Delaware.

200. The State of Delaware paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Delaware funds used to advance the interests of the State of Delaware paid claims and incurred losses, as a result of Defendants' wrongful conduct.

201. By reason of such false and/or fraudulent claims, the State of Delaware has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

202. Pursuant to Del. Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants.

COUNT IX

Violation of the District of Columbia
False Claims Act
(D.C. Code Ann. § 2-308.03 *et seq.*)

203. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

204. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the District of Columbia and/or to contractors, grantees, or other recipients of the District of Columbia funds used to advance the interests of the District of Columbia, false and fraudulent claims for in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the District of Columbia.

205. The District of Columbia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the District of Columbia funds used to advance the interests of the District of Columbia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

206. By reason of such false and/or fraudulent claims, the District of Columbia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

207. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT X

Violation of the Florida False Claims Act
(Fla. Stat. Ann. § 68.081 *et seq.*)

208. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

209. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Florida and/or to contractors, grantees, or other recipients of the State of Florida funds used to advance the interests of the State of Florida, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Florida.

210. The State of Florida paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Florida funds used to advance the interests of the State of Florida paid claims and incurred losses, as a result of Defendants' wrongful conduct.

211. By reason of such false and/or fraudulent claims, the State of Florida has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

212. Pursuant to Fla. Stat. Ann. § 68.082.2, the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XI

Violation of the Georgia False Medicaid Claims Act (Ga. Code Ann. § 49-4-168.1 *et seq.*)

213. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

214. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Georgia and/or to contractors, grantees, or other recipients of the State of Georgia funds used to advance the interests of the State of Georgia, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Georgia.

215. The State of Georgia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Georgia funds used to advance the interests of the State of Georgia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

216. By reason of such false and/or fraudulent claims, the State of Georgia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

217. Pursuant to Ga. Code Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XII

Violation of the Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21 *et seq.*)

218. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

219. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Hawaii and/or to contractors, grantees, or other recipients of the State of Hawaii funds used to advance the interests of the State of Hawaii, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Hawaii.

220. The State of Hawaii paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Hawaii funds used to advance the interests of the State of Hawaii paid claims and incurred losses, as a result of Defendants' wrongful conduct.

221. By reason of such false and/or fraudulent claims, the State of Hawaii has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

222. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XIII

Violation of the Illinois Whistleblower Reward and Protection Act (740 Ill. Comp. Stat. § 175/1 *et seq.*)

223. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

224. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Illinois and/or to contractors, grantees, or other recipients of the State of Illinois funds used to advance the interests of the State of Illinois, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Illinois.

225. The State of Illinois paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Illinois funds used to advance the interests of the State of Illinois paid claims and incurred losses, as a result of Defendants' wrongful conduct.

226. By reason of such false and/or fraudulent claims, the State of Illinois has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

227. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XIV

Violation of the Indiana False Claims and Whistleblower Protection Act (Ind. Code § 5-11-5.5-1 *et seq.*)

228. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

229. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Indiana and/or to contractors, grantees, or other recipients of the State of Indiana funds used to advance the interests of the State of Indiana, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Indiana.

230. The State of Indiana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Indiana funds used to advance the interests of the State of Indiana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

231. By reason of such false and/or fraudulent claims, the State of Indiana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

232. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus the maximum penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XV

Violations of Iowa False Claims Act
(Iowa Code § 685 *et seq.*)

233. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

234. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Iowa and/or to contractors, grantees, or other recipients of the State of Iowa funds used to advance the interests of the State of Iowa, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Iowa.

235. The State of Iowa paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Iowa funds used to advance the interests of the State of Iowa paid claims and incurred losses, as a result of Defendants' wrongful conduct.

236. By reason of such false and/or fraudulent claims, the State of Iowa has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

237. Pursuant to Iowa Code § 685.2, the State of Iowa is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVI

Violation of the Louisiana
Medical Assistance Programs Integrity Law
(La. Rev. Stat. Ann. § 46:439.1 *et seq.*)

238. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

239. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Louisiana and/or to contractors, grantees, or other recipients of the State of Louisiana funds used to advance the interests of the State of Louisiana, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Louisiana.

240. The State of Louisiana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Louisiana funds used to advance the interests of the State of Louisiana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

241. By reason of such false and/or fraudulent claims, the State of Louisiana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

242. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVII

Violations of the Maryland
False Health Claims Act
(Md. Health-General Code Ann. § 2-602 *et seq.*)

243. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

244. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Maryland and/or to contractors, grantees, or other recipients of the State of Maryland funds used to advance the interests of the State of Maryland, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Maryland.

245. The State of Maryland paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Maryland funds used to advance the interests of the State of Maryland paid claims and incurred losses, as a result of Defendants' wrongful conduct.

246. By reason of such false and/or fraudulent claims, the State of Maryland has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

247. Pursuant to Md. HEALTH-GENERAL Code Ann. § 2-602(b)(i) and (ii), the State of Maryland is entitled to three times the amount of actual damages plus the maximum penalty of

248. $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XVIII

Violation of the Massachusetts False Claims Law
(Mass. Gen. Law. ch. 12, § 5A *et seq.*)

249. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

250. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Commonwealth of Massachusetts and/or to contractors, grantees, or other recipients of the Commonwealth of Massachusetts funds used to advance the interests of the Commonwealth of Massachusetts, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the Commonwealth of Massachusetts.

251. The Commonwealth of Massachusetts paid claims and incurred losses, and/or contractors, grantees, or other recipients of the Commonwealth of Massachusetts funds used to advance the interests of the Commonwealth of Massachusetts paid claims and incurred losses, as a result of Defendants' wrongful conduct.

252. By reason of such false and/or fraudulent claims, the Commonwealth of Massachusetts has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

253. Pursuant to Mass. Gen. Law. ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XIX

Violation of the Michigan Medicaid False Claims Act (Mich. Comp. Laws § 400.601 *et seq.*)

254. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

255. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Michigan and/or to contractors, grantees, or other recipients of the State of Michigan funds used to advance the interests of the State of Michigan, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Michigan.

256. The State of Michigan paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Michigan funds used to advance the interests of the State of Michigan paid claims and incurred losses, as a result of Defendants' wrongful conduct.

257. By reason of such false and/or fraudulent claims, the State of Michigan has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

258. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud, three times the amount of actual damages, plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement presented or caused to be presented by the Defendants.

COUNT XX

Violations of the Minnesota False Claims Act
(Minn. Stat. § 15C.01 *et seq.*)

259. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

260. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Minnesota and/or to contractors, grantees, or other recipients of the State of Minnesota funds used to advance the interests of the State of Minnesota, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Minnesota.

261. The State of Minnesota paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Minnesota funds used to advance the interests of the State of Minnesota paid claims and incurred losses, as a result of Defendants' wrongful conduct.

262. By reason of such false and/or fraudulent claims, the State of Minnesota has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

263. Pursuant to Minn. Stat. § 15C.02(a), the State of Minnesota is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXI

Violations of the Montana False Claims Act
(Mont. Code Ann. § 17-8-401 *et seq.*)

264. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

265. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Montana and/or to contractors, grantees, or other recipients of the State of Montana funds used to advance the interests of the State of Montana, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Montana.

266. The State of Montana paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Montana funds used to advance the interests of the State of Montana paid claims and incurred losses, as a result of Defendants' wrongful conduct.

267. By reason of such false and/or fraudulent claims, the State of Montana has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

268. Pursuant to Mont. Code Ann. § 17-8-403, the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXII

Violation of the Nevada False Claims Act
(Nev. Rev. Stat. § 357.010 *et seq.*)

269. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

270. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Nevada and/or to contractors, grantees, or other recipients of the State of Nevada funds used to advance the interests of the State of Nevada, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Nevada.

271. The State of Nevada paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Nevada funds used to advance the interests of the State of Nevada paid claims and incurred losses, as a result of Defendants' wrongful conduct.

272. By reason of such false and/or fraudulent claims, the State of Nevada has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

273. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIII

Violation of the New Hampshire False Claims Act
(N.H. Rev. Stat. § 167:61-a *et seq.*)

274. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

275. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Hampshire and/or to contractors, grantees, or other recipients of the State of New Hampshire funds used to advance the interests of the State of New Hampshire, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of New Jersey.

276. The State of New Hampshire paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Hampshire funds used to advance the interests of the State of New Hampshire paid claims and incurred losses, as a result of Defendants' wrongful conduct.

277. By reason of such false and/or fraudulent claims, the State of New Hampshire has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

278. Pursuant to N.H. Rev. Stat. § 167:61-b the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and

every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXIV

Violation of the New Jersey False Claims Act (N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

279. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

280. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Jersey and/or to contractors, grantees, or other recipients of the State of New Jersey funds used to advance the interests of the State of New Jersey, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of New Jersey.

281. The State of New Jersey paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Jersey funds used to advance the interests of the State of New Jersey paid claims and incurred losses, as a result of Defendants' wrongful conduct.

282. By reason of such false and/or fraudulent claims, the State of New Jersey has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

283. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of allowed under the federal

False Claims Act, 31 U.S.C. § 3729, for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXV

Violation of the New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act (N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*)

284. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

285. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New Mexico and/or to contractors, grantees, or other recipients of the State of New Mexico funds used to advance the interests of the State of New Mexico, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of New Mexico.

286. The State of New Mexico paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New Mexico funds used to advance the interests of the State of New Mexico paid claims and incurred losses, as a result of Defendants' wrongful conduct.

287. By reason of such false and/or fraudulent claims, the State of New Mexico has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

288. Pursuant to N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVI

Violation of the New York False Claims Act
(N.Y. State Fin. Law § 187 *et seq.*)

289. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

290. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of New York and/or to contractors, grantees, or other recipients of the State of New York funds used to advance the interests of the State of New York, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of New York.

291. The State of New York paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of New York funds used to advance the interests of the State of New York paid claims and incurred losses, as a result of Defendants' wrongful conduct.

292. By reason of such false and/or fraudulent claims, the State of New York has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

293. Pursuant to N.Y. State Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVII

Violations of the North Carolina False Claims Act
(N.C. Gen. Stat. § 1-605 *et seq.*)

294. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

295. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of North Carolina and/or to contractors, grantees, or other recipients of the State of North Carolina funds used to advance the interests of the State of North Carolina, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of North Carolina.

296. The State of North Carolina paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of North Carolina funds used to advance the interests of the State of North Carolina paid claims and incurred losses, as a result of Defendants' wrongful conduct.

297. By reason of such false and/or fraudulent claims, the State of North Carolina has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

298. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVIII

Violation of the Oklahoma Medicaid False Claims Act (63 Okla. St. Ann. § 5053 *et seq.*)

299. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

300. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Oklahoma and/or to contractors, grantees, or other recipients of the State of Oklahoma funds used to advance the interests of the State of Oklahoma, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Oklahoma.

301. The State of Oklahoma paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Oklahoma funds used to advance the interests of the State of Oklahoma paid claims and incurred losses, as a result of Defendants' wrongful conduct.

302. By reason of such false and/or fraudulent claims, the State of Oklahoma has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

303. Pursuant to 63 Okla. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXVIX

Violation of the State False Claims Act (Rhode Island)
(R.I. Gen. Laws § 9-1.1-1 *et seq.*)

304. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

305. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Rhode Island and/or to contractors, grantees, or other recipients of the State of Rhode Island funds used to advance the interests of the State of Rhode Island, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Rhode Island.

306. The State of Rhode Island paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Rhode Island funds used to advance the interests of the State of Rhode Island paid claims and incurred losses, as a result of Defendants' wrongful conduct.

307. By reason of such false and/or fraudulent claims, the State of Rhode Island has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

308. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXX

Violation of the Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-181 *et seq.*)

309. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

310. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Tennessee and/or to contractors, grantees, or other recipients of the State of Tennessee funds used to advance the interests of the State of Tennessee, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Tennessee.

311. The State of Tennessee paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Tennessee funds used to advance the interests of the State of Tennessee paid claims and incurred losses, as a result of Defendants' wrongful conduct.

312. By reason of such false and/or fraudulent claims, the State of Tennessee has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

313. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXI

Violation of the Texas
Medicaid Fraud Prevention Law
(Tex. Hum. Res. Code § 36.002 *et seq.*)

314. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

315. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Texas and/or to contractors, grantees, or other recipients of the State of Texas funds used to advance the interests of the State of Texas, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Texas.

316. The State of Texas paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Texas funds used to advance the interests of the State of Texas paid claims and incurred losses, as a result of Defendants' wrongful conduct.

317. By reason of such false and/or fraudulent claims, the State of Texas has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

318. Pursuant to Tex. Hum. Res. Code Ann. § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXII

Violation of the Vermont False Claims Act
(32 V.S.A. § 630 *et seq.*)

319. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

320. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Commonwealth of Virginia and/or to contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the Commonwealth of Virginia.

321. The Commonwealth of Virginia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

322. By reason of such false and/or fraudulent claims, the Commonwealth of Virginia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

323. Pursuant to 32 V.S.A. 631(b)(1), the State of Vermont is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or

fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXIII

Violation of the Virginia Fraud Against Taxpayers Act (Va. Code Ann. § 8.01-216.1 *et seq.*)

324. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

325. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the Commonwealth of Virginia and/or to contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the Commonwealth of Virginia.

326. The Commonwealth of Virginia paid claims and incurred losses, and/or contractors, grantees, or other recipients of the Commonwealth of Virginia funds used to advance the interests of the Commonwealth of Virginia paid claims and incurred losses, as a result of Defendants' wrongful conduct.

327. By reason of such false and/or fraudulent claims, the Commonwealth of Virginia has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

328. Pursuant to Va. Code Ann. § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

COUNT XXXIV

Violation of the Washington State Medicaid Fraud False Claims Act (Rev. Code Wash. § 74.66.0005 *et seq.*)

329. This Complaint incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

330. Defendants knowingly, or acting with deliberate ignorance and/or reckless disregard of the truth, presented and/or caused to be presented, to the State of Washington and/or to contractors, grantees, or other recipients of the State of Washington funds used to advance the interests of the State of Washington, false and fraudulent claims for payment in connection with their introduction of non-cleared and otherwise adulterated and/or misbranded devices that could not be trusted or reasonably relied upon to operate safely and effectively in conformity with FDA-approved design and performance specifications for sale in the State of Washington.

331. The State of Washington paid claims and incurred losses, and/or contractors, grantees, or other recipients of the State of Washington funds used to advance the interests of the State of Washington paid claims and incurred losses, as a result of Defendants' wrongful conduct.

332. By reason of such false and/or fraudulent claims, the State of Washington has been damaged in a substantial amount to be determined at trial and is entitled to a civil penalty as required by law for each violation.

333. Pursuant to Rev. Code Wash. § 74.66.020(1), the State of Washington is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by the Defendants.

WHEREFORE, Relator, on behalf of herself, and acting on behalf of, and in the name of, the Government, respectfully demands and prays that the Court enter judgment against Defendants as follows:

1. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment in the amount of the damage to the Government, trebled as required by law, with civil penalties as required by law, together with all such further relief as may be just and proper;

2. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment awarding Relator the maximum amount available under 31 U.S.C. § 3730(d) for bringing this action, namely twenty-five percent (25%) of the proceeds of the action by judgment or settlement if the Government intervenes in the matter (or pursues its claim through any alternative remedy available to the Government), or, alternatively, thirty (30%) of the proceeds of the action by judgment or settlement of the causes of action, if the Government declines to intervene;

3. On Count I, Count II, and Count III, under the federal False Claims Act, a judgment awarding Relator all reasonable expenses that were necessarily incurred in prosecution of this action, plus all reasonable attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

4. On Counts IV through XXXIV, under the individual state false claims acts, a judgment in the amount of the damage to the individual state, doubled or trebled as permitted by each individual state statute, with civil penalties as required by each individual state statute,

together with all such further relief as may be just and proper;

5. On Counts IV through XXXIV, a judgment awarding Relator the maximum amount available under the individual state false claims acts for bringing this action, plus all reasonable expenses that were necessarily incurred in prosecution of this action, all reasonable attorneys' fees and costs, and all other remedies as provided under individual state false claims acts; and

6. Awarding such other relief for the Government and Relator as this Court deems just and proper.

Dated: March 9, 2021

Respectfully submitted,

KAISER SAURBORN & MAIR, P.C.

By: Daniel Kaiser

Daniel J. Kaiser
William H. Kaiser
30 Broad Street, 37th Floor
New York, New York 10004
Telephone No. (212) 338-9100
Facsimile No. (212) 338-9088
kaiser@ksmlaw.com
kaiserw@ksmlaw.com

KAISER LAW FIRM, PLLC

By: /s/ Geoffrey R. Kaiser

Geoffrey R. Kaiser
926 RXR Plaza
Uniondale, New York 11556-0926
Telephone No. (516) 570-3071
Facsimile No. (516) 570-3071